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(54) Title: TISSUE CONNECTOR APPARATUS AND METHODS

(57) Abstract

A tissue connector assembly having a flexible member and a surgical fastener such as a surgical clip releaseably coupled to the flexible member. A needle may be secured to one end portion of the flexible member with the surgical clip coupled to the other end portion of the flexible member. A locking device may be used to releaseably couple the flexible member to the surgical clip. The tissue connector assembly may have one or more piercing members, each releaseably coupled to the surgical fastener. A flexible member such as a suture may be used to couple one or both piercing members to respective ends of the fastener.

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TISSUE CONNECTOR APPARATUS AND METHODS

FIELD OF THE INVENTION

The present invention relates to instruments and methods for connecting body tissues, tissue and prostheses, tissue and graft or any combination thereof.

BACKGROUND OF THE INVENTION

Minimally invasive surgery has allowed physicians to carry out many surgical procedures with less pain and disability than conventional, open surgery. In performing minimally invasive surgery, the surgeon may make a number of small incisions through the body wall to obtain access to the tissues requiring treatment. Typically, a trocar, which is a pointed, piercing device, is delivered into the body with a cannula. After the trocar pierces the abdominal or thoracic wall, it is removed and the cannula is left with one end in the body cavity, where the operation is to take place, and the other end opening to the outside. A cannula may have a small inside diameter, typically 5-10 millimeters, and sometimes up to as much as 20 millimeters. A number of such cannulas are inserted for any given operation.

A viewing instrument, typically including a miniature video camera or optical telescope, may be inserted through one of these cannulas and a variety of surgical instruments and refractors inserted through others. The image provided by the viewing device may be displayed on a video screen or television monitor, affording the surgeon enhanced visual control over the instruments. Because a commonly used viewing instrument is called an "endoscope," this type of surgery is often referred to as "endoscopic surgery." In the abdomen, endoscopic procedures are commonly referred to as laparoscopic surgery, and in the chest, as thoracoscopic surgery. Abdominal procedures may take place either inside the abdominal cavity (in the intraperitoneal space) or in a space created behind the abdominal cavity (in the retroperitoneal space). The retroperitoneal space is particularly useful for operations on the aorta and spine, or abdominal wall hernia.

Minimally invasive surgery has been used in place of open surgical techniques for operations such as cholecystectomy and anti-reflux surgery of the esophagus and stomach.

This has not occurred in either peripheral vascular surgery or cardiovascular surgery. An important type of vascular surgery is to replace or bypass a diseased, occluded or injured artery. Arterial replacement or bypass grafting has been performed for many years using open surgical techniques and a variety of prosthetic grafts. These grafts are manufactured as fabrics (often from DACRON® (polyester fibers) or TEFLON® (fluorocarbon fibers)) or are prepared as autografts (from the patient's own tissues) or heterografts (from the tissues of animals) or a combination of tissues, semi-synthetic tissues and or alloplastic materials. A graft can be joined to the involved artery in a number of different positions, including end-to-end, end-to-side, and side-to-side. This attachment between artery and graft is known as an anastomosis. Constructing an arterial anastomosis is technically challenging for a surgeon in open surgical procedures, and is almost a technical impossibility using endoscopic minimally invasive techniques.

Many factors contribute to the difficulty of performing arterial replacement or bypass grafting. See generally, Wylie, Edwin J. et al., Manual of Vascular Surgery, (Springer-Verlag New York), 1980. One such factor is that the tissues to be joined must be precisely aligned with respect to each other to ensure the integrity and patency of the anastomosis. If one of the tissues is affixed too close to its edge, the suture can rip through the tissue and impair both the tissue and the anastomosis. Another factor is that, even after the tissues are properly aligned, it is difficult and time consuming to pass the needle through the tissues, form the knot in the suture material, and ensure that the suture material does not become tangled. These difficulties are exacerbated by the small size of the artery and graft. The arteries subject to peripheral vascular and cardiovascular surgery typically range in diameter from several millimeters to several centimeters. A graft is typically about the same size as the artery to which it is being attached. Another factor contributing to the difficulty of such procedures is the limited time available to complete the procedure. The time the surgeon has to complete an arterial replacement or bypass graft is limited because there is no blood flowing through the artery while the procedure is being done. If blood flow is not promptly restored, sometimes in as little as thirty minutes, the tissue the artery supplies may experience significant damage, or even death (tissue necrosis). In addition, arterial replacement or bypass grafting is made more difficult by the need to accurately place and space many sutures to achieve a permanent hemostatic seal. Precise

placement and spacing of sutures is also required to achieve an anastomosis with long-term patency.

Highly trained and experienced surgeons are able to perform arterial replacement and bypass grafting in open surgery using conventional sutures and suturing techniques. A suture needle is attached or "swedged on" to a long, trailing suture material. The needle must be precisely controlled and accurately placed through both the graft and artery. The trailing suture material must be held with proper tension to keep the graft and artery together, and must be carefully manipulated to prevent the suture material from tangling. In open surgery, these maneuvers can usually be accomplished within the necessary time frame, thus possibly avoiding the subsequent tissue damage (or tissue death) that can result from prolonged occlusion of arterial blood flow.

A parachuting technique may be used to align the graft with the artery in an end-to-side anastomosis procedure. With this technique, one or multiple sutures are attached to the graft and artery and are used to pull or "parachute" the graft vessel into alignment with an opening formed in a sidewall of the artery. The graft vessell and artery opening edges may be everted as is known in the art. Among the drawbacks to this procedure are the difficulty in preventing the suture from tangling and the time and surgical skill required to tie individual knots when using multiple sutures. Due to space requirements, this procedure is generally limited to open surgery techniques.

The difficulty of suturing a graft to an artery using minimally invasive surgical techniques has effectively prevented the safe use of this technology, in both peripheral vascular and cardiovascular surgical procedures. When a minimally invasive procedure is done in the abdominal cavity, the retroperitoneal space, or chest, the space in which the operation is performed is more limited, and the exposure to the involved organs is more restricted, than with open surgery. Moreover, in a minimally invasive procedure, the instruments used to assist with the operation are passed into the surgical field through cannulas. When manipulating instruments through cannulas, it is extremely difficult to position tissues in their proper alignment with respect to each other, pass a needle through the tissues, form a knot in the suture material once the tissues are aligned, and prevent the suture material from becoming tangled. Therefore, although there have been isolated reports of vascular anastomoses being formed by minimally invasive surgery, no system

has been provided for wide-spread surgical use which would allow such procedures to be performed safely within the prescribed time limits.

As explained above, anastomoses are commonly formed in open surgery by suturing together the tissues to be joined. However, one known system for applying a clip around tissues to be joined in an anastomosis is disclosed in a brochure entitled, "VCS Clip Applier System", published in 1995 by Auto Suture Company, a Division of U.S. Surgical Corporation. A clip is applied by applying an instrument about the tissue in a nonpenetrating manner, i.e., the clip does not penetrate through the tissues, but rather is clamped down around the tissues. As previously explained, it is imperative in forming an anastomosis that tissues to be joined are properly aligned with respect to each other. The disclosed VCS clip applier has no means for positioning tissues. Before the clip can be applied, the tissues must first be properly positioned with respect to each other, for example by skewering the tissues with a needle as discussed above in common suturing techniques or with forceps to bring the tissues together. It is extremely difficult to perform such positioning techniques in minimally invasive procedures.

Therefore, there is currently a need for other tissue connecting systems.

SUMMARY OF THE INVENTION

The present invention involves apparatus and methods for connecting material, at least one of which is tissue. The invention may, for example, be used to secure one vessel to another, such as in a vascular anastomosis.

According to one aspect of the invention, a tissue connector assembly is provided and comprises a flexible member and a surgical clip which may be releasably coupled to the flexible member. With this construction, a needle may be coupled to the flexible member, which may be in the form of a suture, to facilitate, for example, parachuting suture tissue connecting procedures. The surgical clip may eliminate the need for tying sutures, which requires significant skill, space, and time.

According to another aspect of the invention a tissue connector assembly comprises a needle, a flexible member coupled to the needle, and a locking device coupled to the flexible member. The locking device is adapted for receiving a surgical fastener. Thus, a surgical fastener may be selected based on a desired procedure and coupled to the locking

device to facilitate, for example, parachuting suture tissue connecting procedures as discussed above.

According to another aspect of the invention, a method for connecting tissues includes drawing portions of tissue together with a clip assembly and securing the tissue portions together with the clip assembly.

According to another aspect of the invention, multiple portions of material are drawn together with a tissue connector assembly having a clip in an open position. At least one of the portions of material is tissue. The clip is closed to secure the material portions therein. The materials may be drawn together by pulling the tissue connector assembly with at least a portion of the clip positioned in the materials. A needle may be used to insert the tissue connector assembly into the material. A portion of the tissue connector assembly may be manipulated to simultaneously actuate closure of the clip and release the needle from the clip.

According to another aspect of the invention, a tissue connector assembly is inserted through graft and target vessels with the graft vessel being spaced from the target vessel. The tissue connector assembly has a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least one end of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

According to another aspect of the invention, a tissue connector assembly is inserted through the graft and target vessels with the graft vessel being spaced from the target vessel and the tissue connector assembly having a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least a portion of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

According to another aspect of the invention a tissue connecting assembly may include multiple piercing members coupled to a surgical fastener. According to one embodiment, a tissue connector assembly is provided comprising a surgical fastener, such as a surgical clip, a first tissue piercing member and a second tissue piercing member. The fastener may be adapted to assume a loop configuration. The fastener has a first end portion and a second end portion. The first tissue piercing member is coupled to the first

end portion and the second tissue piercing member is coupled to the second end portion. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer walls of material, such as tissue, which may eliminate or minimize the possibility of dislodging material from the inner wall of a vessel, for example.

According to another aspect of the invention, a flexible member, such as a suture, may be provided between at least one piercing member and the fastener to facilitate threading the fastener and/or "parachute" techniques, for example.

According to another aspect of the invention, synchronized piercing member release mechanisms may be provided. In one embodiment, the tissue connector assembly may include a first coupling, which couples the first tissue piercing member and first end portion of the surgical fastener, and a second coupling, which couples the surgical fastener second end portion and second piercing member. The first coupling releases the other coupling in response to releasing the first coupling. According to one aspect of this embodiment, multiple tissue piercing members may be decoupled from the surgical fastener with one release actuator. According to another aspect, the piercing members may be decoupled essentially simultaneously.

The above is a brief description of some deficiencies in the prior art and advantages of the present invention. Other features, advantages, and embodiments of the invention will be apparent to those skilled in the art from the following description, accompanying drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a tissue connector assembly of the present invention;

Fig. 1A is a partial sectional view illustrating an alternate construction of flexible member 18 of Fig. 1;

Fig. 1B is a partial sectional view illustrating yet another construction of flexible member 18 of Fig. 1;

Figs. 2A-2E diagrammatically illustrate a method of aligning and connecting graft and target vessels with the single piercing member tissue connector assembly of Fig. 1, where Fig. 2A shows two tissue connector assemblies threaded through a graft and target

vessel, Fig. 2B shows a further step in connecting the graft and target vessel, Fig. 2C shows a further step for connecting the graft and target vessel with the fastener positioned in the graft and target vessels, Fig. 2D shows the graft vessel connected to the target vessel, and Fig. 2E shows a front view of the connected graft and target vessels of Fig. 2D, with portions broken away to show detail;

Fig. 2F is an enlarged view of the tissue connection shown in Fig. 2E;

Fig. 2G shows an alternate method for connecting the graft vessel to the target vessel with the tissue connector assembly of Fig. 1;

Figs. 3A, 3B and 3C show a fastener which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17 , for example, where Fig. 3A is a top view of the fastener in a closed position, Fig. 3B is a side view of the fastener of Fig. 3A, and Fig. 3C is an enlarged view of the fastener of Fig. 3A in an open position;

Fig. 4 is a top view of another fastener configuration, which can be used with the tissue connector assembly of Fig. 1, 9, 10 or 17, for example;

Figs. 5A and 5B show yet another fastener configuration which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17, for example, where Fig. 5A shows the fastener in a closed position and Fig. 5B is a side view of the fastener of Fig. 5A;

Fig. 6A-6F show further fastener configurations which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17, for example where Fig. 6A is a top view of a fastener in a closed position, Figs. 6B, 6C and 6D are top views of variants of that shown in Fig. 6A, Fig. 6E is a side view of Fig. 6D taken along line 6E--6E of Fig. 6D, and Fig. 6F is an example of a graft to thick tissue anastomosis using the fastener shown in Fig. 6D;

Figs. 7A, 7B and 7C illustrate a release mechanism which can be used with any of the fasteners described above and the tissue connector assembly of Figs. 1, 9, 10 or 17, for example, where Fig 7A shows the restraining device in cross-section and in a locked position, Fig. 7B is a transverse cross-sectional view of the restraining device taken in a plane along line 7B--7B of Fig. 7A , and Fig. 7C is a cross-sectional view of the restraining device of Fig. 7A in an unlocked position;

Fig. 8 is an alternate embodiment of a restraining device;

Fig. 9 is a front view of another embodiment of a single piercing member tissue connector assembly according to the present invention and shown in an open position.

Fig. 10 is a perspective view of a tissue connector assembly constructed in accordance with the principles of the present invention;

Figs. 11A, 11B and 11C illustrate another release mechanism which can be used with any of the fasteners or tissue connector assemblies described above, where Fig 11A shows the restraining device in cross-section and in a locked position, Fig. 11B is a transverse cross-sectional view of the restraining device taken in a plane along line 11B--11B of Fig. 11A, and Fig. 11C is a cross-sectional view of the restraining device of Fig. 11A in an unlocked position;

Figs. 12A-12E illustrates yet another release mechanism which can be used with any of the fasteners described above, where Fig. 12A shows a perspective view of the retaining device coupled with a fastener, Fig. 12B is a sectional view of the retaining device of Fig. 12A, Fig. 12C is a transverse cross-sectional view of the restraining device taken along line 12C-12C in Fig. 12B, Figs. 12D and 12E are perspective and end views of the restraining device, respectively, showing the device depressed for release of the fastener; and Fig. 12F shows the retaining device of Fig. 12A with an adapter for coupling to the other end of the fastener;

Figs. 13A-13C show a synchronized fastener release system, where Figs. 13A and 13C are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 13B is a sectional view taken along lines 13B-13B in Fig. 13A;

Figs. 13D-13F show another synchronized fastener release system where Figs. 13D and 13E are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 13F is a transverse cross-sectional view taken along line 13F-13F in Fig. 13E;

Figs. 14A and 14B are partial sectional views of another release mechanism in a coupled and decoupled state, respectfully;

Figs. 15A and 15B are partial sectional views of a further release mechanism in a coupled and decoupled state, respectfully;

Figs. 16A and 16B are partial sectional views of yet another release mechanism in a coupled and decoupled state, respectfully;

Fig. 17A is a front view of a another embodiment of a tissue connector assembly of the present invention;

Fig. 17B is a sectional view of a piercing member and release mechanism combination, which can be used in the embodiment, illustrated in Fig. 17A;

Figs. 18A-18D diagrammatically illustrate a method of aligning and connecting graft and target vessels with the multiple piercing member tissue connector assembly of Fig. 10, where Fig. 18A shows two such tissue connector assemblies threaded through a graft and target vessel, Fig. 18B shows a further step in connecting the graft and target vessel with the tissue connector assembly fastener is positioned in the target vessel, Fig. 18C shows yet a further step where the graft has been brought into position over the opening formed in the target vessel and the tissue connector assembly fastener positioned through the walls of the graft and target vessel and Fig. 18D shows the fasteners released from the tissue connector assembly of Fig. 10 and securing the graft and target vessel together with additional laterally disposed fasteners; and

Fig. 18E is a partial sectional view of the graft and target vessels with the tissue connector assembly fasteners of Fig. 1 in place prior to placement of additional lateral fasteners.

Corresponding reference characters indicate corresponding elements throughout the drawings.

DESCRIPTION OF THE INVENTION

The present invention generally involves methods and devices for manipulating, aligning and/or connecting tissues, tissue and prosthesis, tissue and graft, or any combination thereof. As used herein, the term graft includes any of the following: homografts, autologous grafts, xenografts, allografts, alloplastic materials, and combinations of the foregoing. Tissue connector assemblies are disclosed, which, for example, may be used in vascular surgery to replace or bypass a diseased, occluded, or injured artery by connecting a graft vessel to a coronary artery or vein in an anastomosis as shown in Figs. 2A-2G or 18A-E. Assemblies constructed in accordance with the invention may be used in open surgical procedures or in minimally invasive or endoscopic procedures for attaching tissue located in the chest, abdominal cavity, or retroperitoneal space. It should be understood, however, that these examples are provided for illustration and are not intended to limit the scope of the invention.

Single or multiple piercing member embodiments are described herein. According to one aspect of the single member embodiment, a piercing member, which may comprise a needle, is releaseably coupled to a fastener. The piercing member may be attached to a flexible member, such as a suture, which in turn is releaseably coupled to the fastener. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member). For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releaseably lock or secure the fastener to the flexible member (or piercing member).

Referring now to the drawings, and first to Fig. 1, a tissue connector assembly constructed according to the principles of the present invention is shown and generally indicated with reference numeral 10. The tissue connector assembly 10 may be used to manipulate and align tissues, or tissue and prosthesis with respect to each other and thereafter connect the tissues or tissue and prosthesis together (Figs. 2A-2G).

In the embodiment shown in Fig. 1, the tissue connector assembly 10 generally comprises a tissue piercing or penetrating member 16, a flexible member 18, and a fastener or surgical clip 20. A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (or coupling member) generally indicated at 28, is connected to the fastener 20 for holding the fastener in a deformed configuration as further described below. Although a particular fastener and accompanying restraining device is shown in Fig. 1, it should be understood that any suitable fastener can be used therein or any of the tissue connector assemblies described herein, including but not limited to the alternate fastener configurations described below. For example, the fastener may be a plastically deformable clip or may comprise two or more parts, at least one of which is movable relative to the other part, such as with a hinged clip. Further, other piercing member release mechanisms can be used with or without restraining devices depending on the fastener construction.

Piercing or penetrating member 16, which may be in the form of a needle (such as a 7-0 or 8-0 needle), has a sharp pointed tip 30 at its distal end for penetrating tissue. Member 16 may be bent as shown in Fig. 1, for example. The diameter of at least a portion of member or needle 16 is preferably greater than the diameter of flexible member 18 so

that the flexible member can easily be pulled through an opening formed in the tissue by the needle. The distal end of member or needle 16 is preferably rigid to facilitate penetration of tissue. The remaining length of member or needle 16 may be rigid or flexible to facilitate movement of the needle through the tissue as further described below. The tip 30 of member or needle 16 may have various configurations and may, for example, be conical, tapered, or grounded to attain a three or four facet tip. Member or needle 16 may be made from stainless steel or any other suitable material, such as a polymeric material. It is to be understood that member or needle 16 may have a shape or radius of curvature other than the one shown, without departing from the scope of the invention. Member or needle 16 may also be integrally formed with the flexible member 18 (e.g., both needle and flexible member formed of the same material.)

Flexible member 18 may be in the form of a suture formed from conventional filament material, metal alloy such as nitinol, polymeric material, or any other suitable material. The material may be non-stretchable or stretchable, solid or hollow, and have various cross-sectional diameters. The flexible member or suture may have a cross-sectional diameter of .003 inch, for example. The diameter and length of the suture will vary depending on the specific application. The suture may be attached to the needle 16 by crimping or swaging the piercing member or needle onto the suture, gluing the suture to the piercing member or needle, or any other suitable attachment method. Flexible member 18 may have cross-sectional shapes other than the one shown herein and may have other constructions as well.

Referring to Fig. 1A, an alternate flexible member construction is shown. Flexible member 18^1 generally comprises a flexible filament 14, which may be in the form of a metal wire, and tube or sleeve 15, which may be in the form of a hollow suture. Tube 15 surrounds filament 14 with one end of the filament 14 secured to piercing member 16 and its other end secured to coupling 28 with glue, for example. The filament may provide kink resistance and pull strength (to minimize or eliminate stretch), and is especially advantageous when using very thin material for tube 15. Tube 15 may, for example, comprise polymeric materials such as polyurethane or polyester. It is noted that at least the portions of the tube adjacent to needle 16 and coupling 28 have the same diameter as the portions of the coupling and needle adjacent thereto. This eliminates the need for the

tapered portions 5 and 6 shown in Fig. 1 (portion 2 and 3 of Fig. 10) other transition sections to minimize or eliminate the step between the flexible member and needle and/or the flexible member and the coupling. Of course, the diameter of the entire flexible member may be the same as that of the coupling and the portion of the needle adjacent to the flexible member as indicated in Fig. 1A.

Referring to Fig. 1B, another hollow flexible member construction is shown. Flexible member 18^{11} comprises tube or sleeve 15, which may be in the form of a hollow suture. Tube 15 is secured to piercing member or needle 16 and coupling 28 through posts or anchors 4, which in turn, are secured to piercing member or needle 16 and coupling 28. The relative dimensions of tube 15 as compared to needle 16 and coupling 28 may be the same as those describe in connection with Fig. 1A for the same reasons.

Referring to Figs. 3-6, one embodiment of a fastener (e.g., fastener 20) comprises a deformable wire 34 made of a shape memory alloy. A nickel titanium (nitinol) based alloy may be used, for example. The nitinol may include additional elements which affect the yield strength of the material or the temperature at which particular pseudoelastic or shape transformation characteristics occur. The transformation temperature may be defined as the temperature at which a shape memory alloy finishes transforming from martensite to austenite upon heating (i.e., A_f temperature). The shape memory alloy preferably exhibits pseudoelastic (superelastic) behavior when deformed at a temperature slightly above its transformation temperature. At least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration. When the wire is positioned within the tissue in its undeformed configuration, a residual stress is present to maintain the tissue tightly together (See e.g., Figs. 2F). In order for the pseudoelastic wire to retain sufficient compression force in its undeformed configuration, the wire should not be stressed past its yield point in its deformed configuration to allow complete recovery of the wire to its undeformed configuration. The shape memory alloy is preferably selected with a transformation temperature suitable for use with a stopped heart condition where cold cardioplegia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used, as is well known by those skilled in the art.

The cross-sectional diameter of the wire and length of the wire will vary depending on the specific application. The diameter "d" of wire 34 may be, for example, between 0.001 and 0.015 inch. For coronary bypass applications, the diameter is preferably between 0.001 and 0.008 inch with a diameter D of the loop (Fig. 3A) being between 0.0125 and 0.0875 inch. As shown in Fig. 3A and 3B, the wire 34 has a circular cross-sectional shape and a generally ring or loop shaped configuration when a closed position. The diameter D of the loop of the fastener 20 (with coil 26, which may be platinum) in its closed position is preferably sized to prevent movement between adjacent tissues. It is to be understood, however, that the wire may have other cross-sectional shapes such as rectangular, or may be formed from multiple strands without departing from the scope of the invention.

One end of wire 34, which may be referred to as the proximal end of wire 34, may include an enlarged portion 36 having a cross-sectional area greater than the cross-sectional area of the wire and diameter of the coil to resist the coil from passing thereover. Alternatively, enlarged portion 36 may have a cross-section that allows the coil to be pulled over the enlarged portion. For example, the cross sectional diameter of the enlarged portion may be about equal to the coil diameter. The enlarged portion 36 also may be provided to cooperate with a release mechanism as will be discussed in more detail below. Enlarged portion 36 may be formed by attaching a member to the end of wire 34 by welding, gluing or other suitable attachment means or may be formed integrally with the wire by deforming the end of the wire. The other end of wire 34, which may be referred to as the distal end of wire 34, also may include an enlarged portion 38 for engagement with a restraining device, such as restraining device 24 (see. e.g., Fig. 1), or a locking device or release mechanism, such as release mechanism 28 (see e.g., Fig. 1), as further described below. The enlarged portion 38 may be formed by deforming the end of wire 34 by swaging or arc welding, or attaching an enlarged portion to the end of the wire by welding, swaging, or other suitable means. Although enlarged portions 36 and 38 are shown with spherical and cylindrical configurations, other configurations or configuration

combinations can be used. For example, both enlarged portions may be spherical or cylindrical, or portion 36 may be cylindrical and portion 38 spherical.

Referring to Figs. 3A-C, fastener 20 is shown in open and closed configurations. When wire 34 is in an undeformed or closed configuration (position or state), the fastener is closed (as shown in Figs. 3A and 3B) for keeping or connecting tissue together, and when wire 34 is in a deformed or open configuration (position or state), the fastener is open (as shown in Fig. 3C) for insertion of the wire into tissue. As discussed above, wire 34 is in its closed configuration when in a relaxed state. Wire 34 is preferably not deformed past its yield point in its open position. Accordingly, it may have a U-shaped configuration in its open position to facilitate insertion of the wire through the tissue. It is to be understood that U-shaped configuration may be alternatively substituted by an equivalent structure or configurations such as C-shaped, V-shaped, J-shaped, and other similarly shaped configurations. Wire 34 is moved from its closed position to its open position by a restraining device, as further described below. When in its closed position, wire 34 forms a loop with the ends of the wire in a generally side-by-side or overlapping orientation (Fig. 3B).

Wire 34 may be formed in the above described shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-500 degrees Celsius for approximately 5 to 30 minutes. Wire 34 is then air quenched at room temperature. The mandrel may have a constant diameter or may be conical in shape.

Referring to Fig. 4, an alternate configuration of fastener 20 in its closed position is shown, and generally indicated with reference numeral 40. Fastener 40 forms a spiral configuration in its closed position for trapping the tissue within a loop formed by the spiral. In its open position, the fastener 40 is configured to form less than a full 360 degree turn, and may be made to have an open position as shown in Fig. 3C, for example.

Referring to Figs. 5A and 5B, another configuration of fastener 20 is shown in its closed position, and is generally designated with reference numeral 41. Fastener 41 is formed in a spiral about a central longitudinal axis A. As shown in Fig. 5B, fastener 41 has a generally conical shape along the longitudinal axis A, with a decreasing diameter as the radius of curvature of fastener 41 decreases. Fastener 41 has an inner end portion 45 and an outer end portion 47, with the enlarged portion 38 of the wire being disposed at the outer

end portion for engagement with the restraining device 24 as shown, for example, in Fig. 3C.

Referring to Fig. 6A, a modification of fastener 41 is shown, and generally indicated with reference numeral 43. Fastener 43 is similar to fastener 41 described above, except that enlarged portion 38, which is adapted for engaging a restraining device or releasable locking mechanism, is positioned at the inner end portion 45 of the fastener. Placement of restraining device 24 at the inner end portion 45 of fastener 43 may increase the compression force of the wire in its undeformed position on the tissue and decreases the surface area of the fastener exposed to blood flow. Additionally, one or both ends of the fastener may extend in a substantially straight direction from the curved form of the wire 34, as shown in Figs. 6B-6F. These fasteners are the same as that shown in Fig. 6A with the exception of an added straight section 38' (Fig. 6B), additional straight sections 36' and 38' and a stop "S" (Fig. 6C) and two additional straight sections 36' and 38', a stop and a further quarter turn (Figs. 6D and 6E). The configurations shown in the order of Fig. 6A-6E accommodate fasteners of increasing size. The extensions 36' and 38' preferably extend for a length equal to about two to three times the outside diameter of the coil 26 (as compared to the diameter of the loop) or about 0.010 to 0.020 inches. These extensions may allow the release mechanisms to operate more efficiently and also may simplify manufacture of the fastener.

It is noted that one extension 36' or 38' for use with single needle embodiment such as shown in Figs. 1 or 9, for example. However, the single needle embodiments are not limited to only one extension, and may employ a two extension fastener configuration as well.

The fasteners shown in Figs. 6A or 6B may be embodied by an 8-0 clip size (wire 34), having a cross-sectional thickness of about 0.035 inches, which, in the closed configuration shown, forms an inner loop having a diameter D_1 of about 0.017 inches and an outer loop dimension D_2 horizontally measured from inside of the loop) of about 0.021 inches. In the open configuration the clip forms a U-shape with a depth of the U-shape being about 0.032 inch (0.8mm).

Figs. 6C, 6D and 6E show configurations with two extensions 36' and 38' and which further include a stopper "S", preferably slideably mounted onto the wire 34 in the

vicinity of the transition from a curved wire portion, to the relatively straight extension 38'. The stopper is between discrete srpings 26 and 26[1] and held in place thereby. This embodiment is particularly advantageous for anastamosing a relatively thin-walled vessel to a relatively thick-walled vessel (e.g. the aorta or other large vessel), where an extension acts to prevent the relatively thin-walled vessel from sliding into the anastomosis site and out of the preferred position where it is to be fixed, as is illustrated in Figure 6F.

For example, this fastener design may be embodied by a 6-0 wire (wire 34) having a cross-sectional thickness of about 0.045 inches, which, in the closed configuration shown, forms an inner loop having a diameter D_1 of about 0.060 inches and an outer loop dimension D_2 of about 0.065 inches. In the open configuration the fastener forms a U-shape with a depth of the U-shape being about 0.07-0.09 inch (1.5 to 2 mm).

It is to be understood that the fasteners may have undeformed or deformed configurations different than those shown herein without departing from the scope of the invention. In addition, a locking clip (not shown) may also be attached to connect the ends of the fastener (such as fastener 20, 40, 41, 43, 43, 43^{1}, 43^{11}, 43^{111}) when the fastener is in its closed position to prevent possible opening of the fastener over time. The locking clip may also be integrally formed with one end of the fastener.

As shown in Fig. 3C, wire 34 is surrounded by spring or coil 26 which, along with the locking device 28, restrains the wire in its deformed configuration. Coil 26 comprises a helical wire forming a plurality of loops which define a longitudinal opening 44 for receiving the shape memory alloy wire 34. Coil 26 may be formed from a platinum alloy wire having a cross-sectional diameter of approximately 0.0005-0.005 inch, for example. The helical wire may have other cross-sectional shapes and be formed of different materials. Coil 26 is preferably sized so that when in its free (uncompressed state) it extends the length of wire 34 with one end adjacent to enlarged portion 36 at the proximal end of the wire and the other end adjacent to enlarged portion 38 at the distal end of the wire. It is to be understood that the coil may not extend the full length of the wire. For example, a flange or similar device may be provided on an intermediate portion of wire 34 to limit movement of the coil along the length of the wire.

When coil 26 is in its free state (with the wire in its undeformed configuration), loops of the coil are generally spaced from one another and do not exert any significant

force on the wire 34 (Figs. 3A and 3B). When the coil 26 is compressed (with wire 34 in its deformed configuration), loops of the coil on the inner portion 46 of the coil are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion 48 of the coil are spaced from one another (Fig. 3C). This is due to the compressed inner arc length of coil 26 and the expanded outer arc length of the coil. The compression of the loops on the inner portion 46 of coil 26 exerts a force on the inner side of wire 34 which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). The end of coil 26 adjacent enlarged portion 36 is held in a fixed position relative to wire 34. The opposite end of coil 26 is free to move along wire 34 and is held in place when the coil is in its compressed position by locking device 28. It should be understood, however, that a coil (not shown) having sufficient stiffness, for example, may be used where adjacent loops do not contact one another when the coil is compressed to force wire 34 into an open position.

Referring to Figs. 7A-7C, one embodiment of a releasable locking device or release mechanism, is shown. Releasable locking device 28a is adapted for releaseably coupling a fastener (such as any of the fasteners shown in Figs. 3-6) to a flexible member (such as flexible member 18, 18^{1} or 18^{11}) is shown and generally designated with reference numeral 28a. Release mechanism 28a comprises a flexible tubular member 50 having a distal end portion 52 and is shown with a tapered section or sleeve 2 (or 56), which in turn is coupled to the flexible member. Tapered section or sleeve 2 (or 56), which provides a transition between the flexible member and fastener for insertion of the fastener and locking device through tissue, may be a separate member coupled to tubular member 50 or be formed integrally therewith. Tubular member 50 further includes a proximal end portion 54 releasably attached to wire 34. In this manner, release mechanism 28a releaseably couples the flexible member and needle to the surgical fastener such as fastener 20. In addition to releasably coupling the flexible member and needle to the fastener, the locking device or release mechanism compresses coil 26 to bias the fastener or surgical clip 20 in its open configuration. Although a straight tapered section is shown in Figs. 7A and 7C, the tapered section may be curved as well as shown in Fig. 1 and generally designated with reference numeral 56. More specifically, one may use a straight or curved tapered section in any of the tissue connector assemblies disclosed herein. When a curve is used, it preferably is

sufficiently curved to facilitate passing the tissue connector assembly through connecting tissue in an anastomosis, for example. Tapered portion 2 or 56 may be formed from a metal alloy such as stainless steel or a suitable polymeric material and may be solid or in the form of a sleeve as noted above. It may be flexible. Generally, the tapered section 2 (or 56) or any other tapered section gradually diminishes in diameter to provide a smooth, non-stepped transition between the relatively small diameter of the flexible member to the larger diameter of locking device 28 such as locking device 28a. The flexible member such as flexible member 18 may be swaged into the tapered section, or a heat shrink plastic covering may hold the flexible member in place. The locking device may also be curved.

Tubular member 50 is movable between a locked position (Figs. 7A and 7B) for holding coil 26 in its compressed position and wire 34 in its deformed position, and an unlocked position (Fig. 7C) for inserting or releasing the wire and coil. Referring to Figs. 7B and 7C, three slots 58 are shown formed in tubular member 50 extending from the proximal end 54 of the member and along at least a portion of the member. Slots 58 are provided to allow the proximal end 54 of tubular member 50 to open for insertion and removal of wire 34. It is to be understood that the number of slots 58 and configuration of the slots may vary, or tubular member 50 may be formed to allow expansion of proximal end 54 without the use of slots.

Proximal end 54 of tubular member 50 includes a bore 62 having a diameter slightly greater than the outer diameter "d" of wire 34, but smaller than the diameter of enlarged portion 38 at the distal end of the wire and the outer diameter of the coil 26. Bore 62 extends into a cavity 64 sized for receiving the enlarged portion 38 of wire 34. Tubular member 50 may be described as having an annular flange 61 for releasably securing enlarged portion 38. As shown in Fig. 7C, upon application of an inwardly directed radial squeezing force on the tubular member 50, proximal end 54 of the tubular member is opened to allow for insertion or removal of wire 34. When the force is released, the tubular member 50 moves back to its locked position and securely holds wire 34 in place and compresses the coil 26 as shown in Fig. 7A. A disc 51 may be inserted into tubular member 50 to act as a fulcrum and cause the proximal end 54 of the tubular member to open. Alternatively, disc 51 may be integrally formed with tubular member 50. As shown in Fig. 7A, the length ℓ of the bore 62 or flange 61 determines the amount of compression

of the coil, which in turn determines the amount of deformation of wire 34. The greater the length ℓ of bore 62, the greater the compression of coil 26 and the more straightening of wire 34 will undergo. The compression of coil 26 is preferably limited so that wire 34 is not stressed beyond its yield point. This allows wire 34 to revert back to its original undeformed configuration and apply sufficient pressure to hold the connected tissue together.

An alternate embodiment of the restraining device is shown in Fig. 8, and generally indicated with reference numeral 70. The restraining device 70 is used with a tubular (hollow) shape memory alloy wire 72 (having a memory loop shape) and comprises an elongated member (or mandrel) 74 sized for insertion into the wire or tube. The mandrel 74 is preferably formed from a material which is stiffer than the material of the wire 72 so that upon insertion of the mandrel into the wire, the wire is deformed into its open position. The restraining device 70 includes a stop 76 located at the proximal end of the wire 72 and which may be attached thereto such as by gluing, swaging or welding. The stop operates to prevent the fastener from being pulled through the tissue, and limits axial movement of the mandrel 74 in the proximal direction (to the right as viewed in Fig. 8). The distal end of the mandrel 74 is attached to the suture 18 and includes a tapered portion 78. The tapered portion 78 may be a sleeve or may be solid and may be formed from any suitable metal or polymeric material, for example. It is to be understood that other types of restraining devices may be used without departing from the scope of the invention.

Another tissue connector assembly is shown in Fig. 9 and generally indicated with reference numeral 100. The tissue connector assembly 100 is the same as the first embodiment 10 except that a needle 102 is attached directly to a locking device 104 with the suture 18 of the first embodiment being eliminated. The tissue connector assembly 100 includes needle 102 (which can be the same as needle 16), a restraining device 108, and a fastener 110. Fig. 9 shows the tissue connector assembly 100 with the fastener in its open (deformed) configuration. Fastener 110 may be the same as the fasteners 20, 40, 41, 43, 43^{I}, 43^{II}, or 43^{III} described herein and shown in Figs. 3-6, for example.

The restraining device 108 comprises a coil 112 (which may be the same as the coils described herein) and the locking device 104. The locking device 104 may be the same as any locking device , except that the distal end is configured for attachment directly

to the needle 102. The needle 102 may be integrally formed with the locking device 104 or may be swaged, welded, threadably attached, or attached by any other suitable means to the locking device. The restraining device also may be the same as described restraining devices 28a, 28b and 28c, for example, or restraining device 70 as shown in Fig. 8.

As noted above, the tissue connector assemblies 10, 100 have many uses. They may be especially useful for minimally invasive surgical procedures including creating an anastomosis between a vascular graft 12 and an artery 14 (Figs. 2A-2G). The anastomosis may be used to replace or bypass a diseased, occluded or injured artery. A coronary bypass graft procedure requires that a source of arterial blood flow be prepared for subsequent bypass connection to a diseased artery. An arterial graft may be used to provide a source of blood flow, or a free graft may be used and connected at the proximal end to a source of blood flow. Preferably, the source of blood flow is one of any number of existing arteries which may be dissected in preparation for the bypass graft procedure. In many instances it is preferred to use the left internal mammary artery (LIMA) or the right internal mammary artery (RIMA), for example. Other vessels which may be used include the saphenous vein, gastroepiploic artery in the abdomen, radial artery, and other arteries harvested from the patient's body as well as synthetic graft materials, such as DACRON® (polyester fibers) or GORETEX® (expanded polytetrafluoroethylene). If a free graft vessel is used, the upstream end of the dissected vessel, which is the arterial blood source, will be secured to the aorta to provide the desired bypass blood flow, as is well known by those skilled in the art. The downstream end of the graft vessel is trimmed for attachment to an artery, such as the left anterior descending coronary (LAD). It is to be understood that the anastomosis may be formed in other vessels or tissue.

Figures 2A-2F show an exemplary use of the tissue connector assemblies 10, 100 for connecting a graft vessel 12 to an artery 14 (target vessel). In this example, two tissue connector assemblies 10 are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies 100 are used to make connections between those made with assemblies 10 (Fig. 2E). The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically.

The patient is first prepped for standard cardiac surgery. After exposure and control of the artery 14, occlusion and reperfusion may be performed as required. An arteriotomy is performed on artery 14 to provide an opening for receiving a graft vessel. After the snared graft vessel 12 has been prepared and made to the appropriate length as would be conventional in the art, a tissue connector assembly 10 is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly 10, the surgeon grasps the needle 16 with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts the needle 16 into the tissue of the graft vessel 12 in a direction from the exterior of the vessel to the interior of the vessel. The surgeon then releases the needle 16 and grasps a forward end of the needle which is now located inside the graft vessel 12 and pulls the needle and a portion of the suture 18 through the vessel. The needle 16 is passed through an opening 120 formed in the sidewall of the artery 14 and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps the needle 16 located outside the artery 14 and pulls the needle and a portion of the suture 18 through the arterial wall. A second tissue connector assembly 10 may be inserted at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies 10 are inserted, the graft vessel 12 is positioned above and aligned with the opening 120 in the sidewall of the artery 14 (Fig. 2A). A section of each suture 18 is located between the graft vessel 12 and artery 14. The fasteners 20 and needles 16 are pulled generally away from the artery 14 to reduce the length of the suture 18 (eliminate slack of the suture) between the vessel 12 and artery and "parachute" the vessel onto the artery (Fig. 2B). The needles 16 are then pulled away from the artery 14 until each fastener 20 is positioned within the graft vessel 12 and artery with one end of each fastener 20 extending from the vessel and the opposite end of each fastener extending from the artery (Fig. 2C). The edges of the graft vessel 12 and artery 14 are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. As shown in Fig. 2F, the tissue is compressed within fastener 20 where the graft and arteriotomy edges may be abutted or everted as is known in the art.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device 28 to release the locking device from the fastener 20. Upon removal of the locking device 28, the coil 26 moves to its free uncompressed state which allows the wire 34 to return to its original undeformed closed position (Fig. 2D). As the wires 34 move to their closed position the adjacent tissues of the graft vessel 12 and artery 14 which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (Figs. 2E and 2F). It should be noted that as the locking device 28 is squeezed two steps are accomplished. The fastener 20 is released from the locking device 28, thus allowing the coil 26 to uncompress and the wire 34 to move to its closed configuration, and the needle 16 is released from the fastener. Thus, in this embodiment, the locking device 28 provides for simultaneous actuating closure of the fastener 20 and release of the needle 16 from the fastener.

The tissue connector assemblies 100 are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten the graft vessel 12 to the artery 14. The needle 102 of the fastener 100 is inserted into the graft vessel 12 from the exterior surface of the graft vessel and pushed through the graft vessel and artery 14 tissue. The needle holder is then used to pull the needle 102 through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device 104 to release the wire and coil 112 from the needle 102. This allows the coil 112 to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies 10 may remain in their open position while the tissue connector assemblies 100 are inserted into the tissue and moved to their closed position. The locking devices 28 of the tissue connector assemblies 10 may subsequently be removed from the fasteners 20 to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies 10, 100 required to sealingly secure the connecting tissues together may vary. For example, only tissue connector assemblies 10 may be used to complete the entire anastomosis.

Although the coil 26 is shown remaining on the wire (Fig. 2D), it is to be understood that the coil 26 may also be removed from the wire 34, leaving only the wire in the connected tissue.

As an alternative to inserting tissue connector assemblies 10 at "heel and toe" locations described above, a number of tissue connectors 10 may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis.

The graft vessel 12 may also be parachuted onto the artery 14 in the method shown in Fig. 2G. The needle is inserted into the graft vessel 12 and artery 14 as described above and the suture 18 is pulled through the vessel so that the fastener 20 is positioned within the vessel and artery. The needles 16 are then pulled away from the artery 14 to "parachute" the graft vessel 12 onto the artery. The anastomosis may then be completed as described above.

Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side anastomosis, connecting various tissue structures including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

According to another embodiment of the invention, multiple tissue piercing members may be provided. More specifically, tissue connecting assemblies constructed according to the present invention may include a plurality of tissue piercing or penetrating members coupled to a surgical fastener. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer wall(s) of material, such as tissue, which may eliminate or minimize the possibly of dislodging material, such as plaque, from the inner wall of calcified arteries, for example, as will become more apparent from the description provided below. In a preferred embodiment, two piercing members, each of which may comprise a needle, are releaseably coupled to a fastener. One or both of the piercing members may be attached to a flexible member, such as a suture,

which in turn is releaseably coupled to the fastener. Double and single flexible member embodiments are illustrated in Figs. 10 and 17, respectively. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member). For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releaseably lock or secure the fastener to the flexible member (or piercing member).

Fig. 10 illustrates one embodiment of a tissue connector assembly with multiple tissue piercing members in accordance with the present invention. Referring to Fig. 10, a tissue connector assembly 11, which generally comprises tissue piercing or penetrating members 16 and 17, flexible members 18 and 19, and a fastener 20 (e.g., a surgical clip) is shown. A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (or coupling member) generally indicated at 28, is connected to fastener 20 for holding the fastener in a deformed or open configuration as will be further described below. Although a particular fastener and accompanying restraining device is shown in Fig. 10, it should be understood that any suitable fastener can be used, including but not limited to the alternate fastener configurations described herein.

Penetrating or piercing member 17 may be made in accordance with the description provided above in connection with penetrating member 16, and, thus may, for example, be in the form of a needle (such as a 7-0 or 8-0 needle) having a sharp pointed tip 31 at its distal end for penetrating tissue. Members 16 and 17 may be the same or differ from one another. Flexible members 18 and 19 may have the same construction. Accordingly, flexible members 18^{1} or 18^{11} may be substituted therefor.

Figs. 11A, 11B and 11C illustrate another release mechanism which is generally designated with reference numeral 28b. Figs. 11A and 11B show the release mechanism in a locked position, and Fig. 11C shows the release mechanism in an unlocked position. Release mechanism 28b comprises a tubular member 80, which has proximal and distal ends 88 and 89, respectively. Tubular member 80 further includes bore 82 formed therein and a cavity or recess 84 extending radially outward from bore 82 into the tubular member. Recess 84 is configured to receive enlarged portion 38 or wire 34 as best illustrated in Fig. 11A. Recess 84 and bore 82 form an annular flange 86, which has an inner diameter less

than that of enlarged portion 38 and, thus, resists removal of the enlarged portion. In the embodiment shown in Fig. 11A-C, three slots 87 are formed in tubular member 80 as in the embodiment shown in Figs. 7A-C. The slots extend longitudinally from the proximal end 88 of tubular member 80 and form fingers 81, which radially expand and release wire 34 upon radial compression of the tubular member as shown in Fig. 11C and as described above in connection with release mechanism 28a. In this embodiment, however, enlarged portion 38 forms a fulcrum. Although three equiangularly spaced slots, which extend parallel to the longitudinal axis are shown as in release mechanism 28a, the number and configuration of the slots may vary, or the tubular member may be formed to allow expansion of the proximal end portion without the use of slots. A tapered section 2 also may be provided as described above in connection with release mechanism 28a.

The release mechanism is generally indicated with reference numeral 28c in Figs. 12A-12E where Figs. 12A-C show the mechanism coupled with a fastener, and Figs. 12D and 12E show the release mechanism depressed for release of the fastener. Locking device or release mechanism 28c comprises a plurality of substantially rigid strands, preferably wires 106, arranged substantially parallel to one another and circularly about a longitudinal axis of the aligned strands, to form a tube-like configuration, as can be seen in the cross-sectional view of Fig. 12C and the perspective view in Fig. 12A. Alternatively, strands 106 may be cables or some other substantially rigid strand elements arranged in the same manner as the wires shown in Figure 12C. Upon arrangement into the circular configuration, the hidden end portions 106a of the strands are coupled to tapered section 2, which is coupled to a piercing member or needle through a flexible member such as flexible member 18.

Preferably, a rod 162 extends from tapered section 2 to facilitate fixation of the strands thereto. The coupling of the strands to tapered section 2 is preferably accomplished by gluing or soldering to rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, rod 162 is preferably glued, soldered or threaded into the needle or transition element. In an alternate arrangement, the flexible member may extend through tapered section 2 and form a substitute structure for rod 162. This may be preferred when the flexible member is a metal wire.

The end portions 106b of the strands in the vicinity of the fastener strands include notches 109 which are formed into the strands to a depth equal to approximately half the diameter of the strand 106. When the strands are arranged in the circular configuration described above, the notches 109 form a chamber 108 configured for receiving and holding enlarged portion 38. Although enlarged portion 38 is shown as having a spherical shape, it may have other shapes including a barrel shape, or other shape that may be easily grasped and easily released. The notches are preferably placed about .015" from the free ends of the strands, but this distance, of course, can be modified, depending upon the amount of compression of spring 26 that is desired when ball 38 is inserted into and held by notches 109.

After placement of ball 38 within chamber 108 formed by notches 109, a shrink wrap layer, preferably a shrink tubing 110 may be provided over at least free end portions 106b of wires or strands 106, and the tubing heated to compress against strands 106 and hold them in place against ball 38, preferably symmetrically against ball 38. Together, tubing 110 and strands 106 effectively hold ball 38 captive within notches 109. Alternatively, other plastic or elastic restraining members may be mounted around the distal portions of the wires or strands to aid in maintaining them in place, preferably symmetrically against ball 38. Still further, strand members may be designed with an elastic spring force sufficient to maintain notches 109 in place with sufficient force to maintain the ball 38 captive therein under the tensile forces normally experienced during a suturing procedure. Although a seven strand embodiment is shown, it should be understood that fewer or more than seven strands may be used. The number of strands may vary depending on, for example, the size of the clip or the size of the strands. Typically, the number of strands may range from two to ten. In a coronary anastomosis, the number of strands preferably will range from five to seven although other numbers may be used.

In assembling, enlarged portion 38 of wire 34 is placed in chamber 108. Tubing 110 is wrapped around at least a portion of the strands (as shown in the drawings) and heated to maintain enlarged portion 38 captive within the cavity formed by the strands. Compression coil or spring 26 is slid over wire 34 and compressed against portions 106b such that the fastener is in its open configuration. Enlarged portion 36 may then be formed or attached to wire 34 to maintain the fastener in its open configuration.

Release mechanism 28c is movable between a locked position (Figs. 12A-12C) and an unlocked position (Figs. 12E and 12F). In the locked position the ball 38 is held within notches 109 and consequently, coil 26 is held in its compressed position, thereby maintaining fastener wire 34 in its deformed or open position. In the unlocked position, ball 38 is released from the notches, thereby allowing the coil 26 to expand, which causes the fastener wire 34 to close. The closure conformation of the wire may be characterized by any of those described above with reference to Figs. 3-6, for example.

Movement of the release mechanism to the open position is accomplished by applying a compressive force to the shrink tube 110 and bundle of strands 106, as shown in Figs. 12D and 12E. Advantageously, the compressive force may be applied at any opposing locations around the circumference of the shrink tube as long as the implement applying the force is oriented at an angle to the strands, preferably substantially perpendicular thereto, to allow the implement to traverse the strands so as to deform the positions thereof when the force is applied. For example, needle holder 111 could be rotated 90° (or virtually any other angle) with respect to the strands 106 as shown in the plane of the drawing, while retaining the capability of deforming the strands to an open position upon application of a compressive force. The compressive force is preferably applied using a standard needle holder 111 or forceps, although other tools could be used, preferably those with applicators narrower than the length of the shrink tube 110. As shown, the strands or wires 106 get distorted from their circular configuration under the compression. This change in shape stretches the shrink tube 110 from a circular configuration to a somewhat elliptical configuration, and removes some of the notches 109 from contact with ball 38, thereby permitting removal of ball 38 from within the chamber previously formed by notches 109 in the closed position.

Referring to Fig. 12F, release mechanism 23c also may be used to releasably couple the other end of the fastener to another flexible member such as flexible member 19, which in turn, is coupled to a needle such as needle 17 as shown in Fig. 1. In this arrangement, a member or stopper 115, which may be annular, is secured to the other end of the fastener or wire 34 to prevent enlarged portion 36 from passing through the compression spring upon release from release mechanism 23c. Other release mechanisms, which provide synchronized release of both needles illustrated in Fig. 10 or 17, also can be used.

Figs. 13A-13F illustrate synchronized fastener release systems. Referring to Figs. 13A-13C, a first synchronized release system is shown in a coupled and decoupled state, respectfully. Although one release mechanism is shown as corresponding to release mechanism 28c, release mechanisms 28a or 28b or any release mechanism which releaseably couples the flexible member or needle to the surgical fastener and effects compression of coil 26 also may be used. At the other end of the fastener or wire 34, a release mechanism which responds to the compressive state of coil 26 and releases the fastener or wire 34 upon release of compressive forces on the coil is shown and generally designated with reference numeral 29a. Release mechanism 29a comprises two members 121 each having a recess 122 formed therein and arranged to form chamber 124 when members 121 are aligned as shown in Fig. 13A. Recesses 122 are configured to retain enlarged portion 36, which is shown with a cylindrical configuration, but may have a spherical or other suitable shape for operatively associating with a suitably configured chamber. Further, members 121 may have semicircular transverse cross sections or some other combination of transverse shapes that can collectively provide the desired chamber to retain enlarged portion 36. The number of members 121 also may vary as would be apparent to one of ordinary skill.

Release mechanism members 121 have tapered ends 126, which are configured for positioning between coil 26 and fastener wire 34 as shown in Fig. 13A. When tapered ends 126 are so positioned and coil 26 is in a compressed state, coil 26 holds tapered ends 126, which are normally biased away from each other as shown in Fig. 13C, sufficiently together to retain enlarged portion 36 within chamber 124. When release mechanism 28c is actuated (e.g., radially compressed) to release enlarged portion 38 of fastener wire 34, coil 26 assumes its relaxed state, thereby releasing tapered ends 126 of release mechanism 29a from the coil and allowing the tapered ends to radially expand and release enlarged portion 36 of fastener wire 34 as shown in Fig. 13C. Accordingly, both needles and flexible members may be decoupled from the fastener when release mechanism 28c is actuated.

Figs. 13D-13F show another synchronized fastener system which is the same as the system shown in Figs. 13A-13C with the exception of release mechanism 29b and the cooperating portion of the fastener or wire 34 being substituted for release mechanism 29a. In this embodiment, an annular member or stopper 115, which may be annular, is slidably

coupled to fastener wire 34. Member 115 is configured to resist passage of coil 26 thereover. Accordingly, member 115 may have an outer diameter slightly greater than at least the portion of the coil adjacent thereto. A tapered or frustoconical member 3' is secured to an end of fastener wire 34, which need not include an enlarged portion. Member 3' is the same as member 3 with the exception that member 3' has a channel 134 for receiving flexible member or suture 19. Channel 134 extends radially outward from bore 132, which is formed through member 3', for receiving the fastener or wire 34.

Flexible member 19 is threaded through channel 134 and between tapered member 3' and annular member 115. When coil 26 is in a compressed state as shown in Fig. 13D, the coil urges member 115 toward tapered member 3' and compresses flexible member 19 therebetween. In this manner, flexible member 19 is secured to the fastener or wire 34. When release mechanism 28c is actuated (e.g., radially compressed) to release enlarged portion 38 of the fastener or wire 34, coil 26 assumes its relaxed state so that annular member 155 may slide away from tapered member 3' and release flexible member 19. Accordingly, both needles and flexible members may be removed from the fastener when release mechanism 28c is actuated. Although a metal flexible member may be used, a polymeric flexible member may be preferred.

Figs. 14A and 14B show another release mechanism generally indicated with reference numeral 29c. Release mechanism 29c includes a sleeve 142, which is slidably mounted over flexible member 19 so that it can be positioned over the flexible member and the fastener or wire to releaseably hold the flexible member and the fastener together. The end portion of the flexible member opposite the needle and the end portion of the fastener or wire to be engaged therewith may be configured to provide interlocking engagement therebetween. In the embodiment shown in Figs. 14A and 14B, the flexible member, which preferably is metal in this example, and the fastener or wire end portions have mating flange and groove configurations. Flexible member 19 includes groove 144a and flange 146a, which mate with or interlockingly engage groove 144b and flange 146b, which are formed in wire 34. When sleeve 142 is moved away from the fastener or wire, the coupling becomes unrestrained and the flexible member and the fastener or wire can be readily separated by removing flanges 146a and 146b from grooves 144a and 144b as shown in Fig. 11B. Member 115 may be secured to fastener wire 34 to prevent the end of

coil 26 adjacent to groove 144b and flange 146b from sliding thereover. Member 115 also may be described as a stopper for spring 26.

Figs. 15A and 15B show another release mechanism, which is generally designated with reference numeral 29d. In this embodiment, tapered member 3 is provided with a bore for receiving both flexible member 19 and the fastener or wire 34. Member or collar 115 may be fixedly secured to the fastener or wire 34 to resist coil movement over the wire and toward the flexible member. The fastener or wire also may be fixedly secured to the inner wall of tapered member 3 by, for example, gluing or welding. One end of the flexible member is tied into a knot such as knot 150. The knot is packed into the bore 152 and the tapered member is swaged or crimped as shown in Figs. 15A and 15B to secure the knot in the bore. The flexible member is cut as shown in Fig. 15B to decouple the flexible member from the fastener.

Figs. 16A and 16B illustrate a further release mechanism, which is generally designated with reference numeral 29e. Release mechanism 29e generally comprises a release member having a cavity formed therein to receive the fastener or wire 34 and a portion configured for severing the fastener wire. This advantageously eliminates the need for a separate cutting tool to separate the suture or needle from the fastener. One example of such a release member is shown as release member 160. Release member 160 has one end which is fixedly secured to tapered member 3 to which flexible member 19 is secured. Alternatively, members 3 and 160 may be integrally formed. Release member 160 is configured to form a cavity 162 therein and may be in the form of a sleeve. Member 160 includes annular flange 164 through which fastener wire 34 is received. Annular flange 164 includes an annular lip 166, which forms a cutting surface or annular blade. Release member 160 also may include an opening for receiving flexible member 19 therethrough as shown in Figs. 16A and 16B. In this example, release member 160 can be fixedly secured to flexible member 19, which, in turn, can be fixedly secured to tapered member 3. Of course, it should be understood that members 160 and 3 can be directly secured to one another or integrally formed as a single piece. When release member 160 is radially compressed as shown in Fig. 16B, annular lip severs fastener wire 34 and decouples flexible member therefrom. Fastener wire 34 may be provided with annular groove 168 to enhance wire fracture. Release member 160 or annular lip 166 may be 400 series stainless

steel or tool steel to facilitate hardening. Other materials that tend to provide an effective cutting tool also may be used. Release member 160, however, should comprise material that provides the desired flexibility. Further, it should be understood that although release member 160 is shown with a generally cylindrical configuration, other configurations may be used. In assembly, member 115, which may be annular, may be swaged, glued or welded to wire 34 to compress coil 34 after the other end of wire has been secured to a locking device or coupling so that the fastener opens as may be done in the embodiments of Figs. 14A and B and 15A and B. Wire 34 may be preformed with groove 168 or the groove formed prior to sliding member 160 over wire 34 so as to engage blade 166 with the groove.

It is to be understood that locking devices other than those described above may be used with the single or double needle embodiment described herein without departing from the scope of the invention. For example, a locking device (not shown) may comprise a tubular member having an opening formed in a sidewall thereof for receiving an end portion of the wire. The end of the wire may be bent so that it is biased to fit within the opening in the sidewall of the tubular member. An instrument, such as a needle holder may then be used to push the wire away from the opening in the tubular member and release the wire from the tubular member. Various other types of locking devices including a spring detent or bayonet type of device may also be used. Further, the fastener or wire end portions may be configured differently than that shown. For example, one or both of the fastener or wire end portions may be provided with grooves instead of enlarged portions and the release mechanisms or locking device arms, such as, for example, fingers 81 or strands 106, may be provided with projections to releaseably engage with the grooves. It is further noted that the release mechanisms disclosed interchanged in the single and double needle embodiments. For example, release mechanisms 28a, 28b and 28c may be used for release mechanism 29 with the inclusion of a fixed stop 115. Release mechanisms 28a, 28b and 28c are also interchangeable in the single needle assemblies.

Fig. 17A is a front view of a another embodiment of a tissue connector assembly of the present invention which is generally designated with reference numeral 211. Tissue connector assembly 211 is the same as tissue connector assembly 11 with the exception that locking device or release mechanism 28 is directly connected to needle 16. Although any

of the release mechanisms 28a-c may be used to couple the fastener to needle 16, release mechanism 28c is shown in Fig. 14B for purposes of illustrating a connection between a locking device and needle 16.

Referring to Fig. 17B, rod 162 extends from needle 16. Rod 162 and needle 16 may be integrally formed or be separate elements secured which are fixed to one another. The coupling of strands 106 to the needle is preferably accomplished by gluing or soldering to the rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, when the rod and needle are discrete elements, the rod is preferably glued, soldered or threaded into the needle. Alternately, rod 162 may extend from or be affixed to a transition element which in turn is affixed to needle 16.

Figures 18A-18D diagrammatically illustrate a method of aligning and connecting graft and target vessels, such as connecting a graft vessel 12 to an artery 14 (target vessel) using tissue connector assemblies 11 and 100. In this example, two tissue connector assemblies 11 are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies 100 are used to make connections between those made with assemblies 11. The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically. It also should be understood that tissue connector assemblies 211 may be substituted for assemblies 11.

The patient is first prepped for standard cardiac surgery. After exposure and control of artery 14, occlusion and reperfusion may be performed as required, an arteriotomy is performed on artery 14 to provide an opening 120 for receiving a graft vessel. After the snared graft vessel 12 has been prepared as would be apparent to one of ordinary skill in the art, a tissue connector assembly 11 is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly 11, the surgeon grasps needle 16 with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts needle 16 into the tissue of graft vessel 12 in a direction from the interior of the vessel to the exterior of the vessel. The surgeon then releases the needle 16 and grasps a forward end of the needle which is now located outside graft vessel 12 and pulls the needle and a portion of suture 18 through the vessel. Needle 17 is passed through

opening 120 formed in the sidewall of the artery 14 and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps needle 17 located outside the artery 14 and pulls the needle and a portion of suture 19 through the arterial wall. A second tissue connector assembly 11 may be inserted as described above at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies 11 are inserted, graft vessel 12 is positioned above and aligned with opening 120 in the sidewall of the artery 14 (Fig. 18A). A section of each assembly is located between graft vessel 12 and artery 14. The needles 16 and 17 are pulled generally away from the artery 14 to reduce the length of the sutures 18 and 19 (eliminate slack of the sutures) between vessel 12 and artery and "parachute" the vessel onto the artery (Fig. 18B). The needles 17 are then pulled away from the artery 14 until each fastener 20 is positioned within the target vessel 14 as shown in Fig. 18B. Needles 16 are then pulled away from graft 12 until the fasteners are positioned with one end of each fastener 20 extending from the vessel and the opposite end of each fastener extending from the artery (Fig. 18C). The edges of the graft vessel 12 and artery 14 are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. The tissue may be compressed as described above with reference to Fig. 2F.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device 28 to release the locking device from the fastener 20. Upon removal of each locking device 28, each coil 26 moves to its free uncompressed state which allows fastener wire 34 to return to its original undeformed closed position (Fig. 18D). As the wires 34 move to their closed position the adjacent tissues of the graft vessel 12 and artery 14 which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (Fig. 18E). It should be noted that as each locking device 28 is squeezed at least two steps are accomplished. The fastener 20 is released from locking device 28, thus allowing coil 26 to uncompress and the wire 34 to move to its closed configuration, and the needle 16 is released from the fastener. Thus, any of the locking devices 28 described above provides for simultaneous actuating closure of the fastener 20 and release of the needle 16 from the fastener. Further, radially

compression of release mechanisms 29 releases needles 17 and sutures 19 from the fasteners. However, if one of the synchronous release systems described with reference to Figs. 13A-13F is used, radial compression of a locking device 28 device will effect essentially simultaneous closure actuation of a respective fastener and release of needles 16 and 17 and sutures 18 and 19.

The tissue connector assemblies 100 are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten graft vessel 12 to artery 14. Needle 16 of fastener 100 is inserted into graft vessel 12 from the exterior surface of the graft vessel and pushed through the graft vessel and artery 14 tissue. The needle holder is then used to pull the needle 16 through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device 28 to release fastener 20 from needle 16. This allows coil 26 to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies 11 may remain with their fasteners in their open position while tissue connector assemblies 100 are inserted into the tissue and moved to their closed position. The locking devices 28 of the tissue connector assemblies 11 may subsequently be removed from the fasteners 20 to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies 11 and 100 required to sealingly secure the connecting tissues together may vary. For example, only tissue connector assemblies 11 may be used to complete the entire anastomosis.

Although coils 26 are shown remaining on the fastener or wire (Fig. 18D), it is to be understood that coils 26 may also be removed from wires 34, leaving only the wires in the connected tissue.

As an alternative to inserting tissue connector assemblies 11 at "heel and toe" locations described above, a number of tissue connector assemblies 11 may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis. It also should be understood that tissue connector assemblies 211 may be used instead of or in conjunction with assemblies 11.

Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side

anastomosis, connecting various tissue structures including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

All references cited above and U.S. Patent Application Serial Nos. 09/090,305 and 09/259,705 are incorporated herein by reference.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. The full scope of the invention is set out in the claims that follow and their equivalents. Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.

WHAT IS CLAIMED IS:

1. A tissue connector assembly comprising a flexible member and a surgical clip, said surgical clip being releasably coupled to said flexible member.

2. The tissue connector assembly of claim 1 wherein said flexible member comprises a suture.

3. The tissue connector assembly of claim 1 further including a needle, said needle being coupled to said flexible member.

4. The tissue connector assembly of claim 1 further including a tapered portion extending between said surgical clip and flexible member.

5. The tissue connector assembly of claim 4 wherein said tapered portion is curved.

6. The tissue connector assembly of claim 1 further comprising a locking device, said locking device having a locked position where said surgical clip is coupled to said flexible member and an unlocked position where said surgical clip is released from said flexible member.

7. The tissue connector assembly of claim 1 wherein said surgical clip comprises a wire.

8. The tissue connector assembly of claim 7 wherein said wire is tubular.

9. The tissue connector assembly of claim 7 wherein said wire has a generally circular transverse cross-section.

10. The tissue connector of claim 7 wherein said wire comprises shape memory material.

11. The tissue connector assembly of claim 7 wherein said wire has a first end portion, a second end portion, and an elongated member therebetween, said first end portion being coupled to said flexible portion, said second end portion having a cross-sectional area greater than a cross-sectional area of said elongated member.

12. The tissue connector assembly of claim 1 wherein said surgical clip has an open configuration and a closed configuration.

13. The tissue connector assembly of claim 12 wherein said surgical clip is in said closed configuration when in a relaxed position.

14. The tissue connector assembly of claim 12 wherein said surgical clip is generally U-shaped when in said open configuration.

15. The tissue connector assembly of claim 12 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

16. The tissue connector assembly of claim 15 wherein said surgical clip spirals around a central longitudinal axis, said surgical clip having a generally conical shape along said longitudinal axis.

17. The tissue connector assembly of claim 16 wherein said surgical clip has an inner end portion and an outer end portion, said inner end portion having a smaller radius than said outer end portion, said inner end portion of said surgical clip being coupled to said flexible member.

18. The tissue connector assembly of claim 12 further comprising a restraining device coupled to said clip and biasing said clip in said open configuration.

19. The tissue connector assembly of claim 18 wherein said restraining device comprises a coil surrounding at least a portion of said surgical clip.

20. The tissue connector assembly of claim 19 wherein said coil comprises a plurality of adjacent loops, said coil being compressed with said plurality of adjacent loops being spaced closer to one another along one side of said coil than along an opposite side of said coil when said surgical clip is coupled to said flexible member.

21. The tissue connector assembly of claim 18 wherein at least a portion of said restraining device remains on said surgical clip when said clip is released from said flexible member.

22. The tissue connector assembly of claim 18 wherein said surgical clip comprises a tubular wire and said restraining device comprises an elongated member positioned within said wire.

23. A tissue connector assembly comprising a needle, a flexible member coupled to said needle, and a locking device coupled to said flexible member and adapted for receiving a surgical fastener.

24. The tissue connector assembly of claim 23 wherein said flexible member is a suture.

25. A tissue connector assembly comprising a suture having first and second end portions, a needle secured to one of said end portions, and a surgical clip coupled to the other of said end portions.

26. The tissue connector assembly of claim 25 wherein said clip comprises a wire.

27. The tissue connector assembly of claim 26 wherein said wire comprises shape memory material.

28. The tissue connector assembly of claim 25 wherein said clip has an open configuration and a closed configuration.

29. The tissue connector assembly of claim 28 wherein said clip is generally U-shaped when in said open configuration.

30. A method for connecting portions of material, at least one portion comprising tissue, the method comprising:

drawing multiple portions of material, at least one of which comprises tissue, together with a tissue connector assembly having a clip in an open position; and

closing said clip and securing said material portions therein.

31. The method of claim 30 wherein said materials are drawn together by pulling said tissue connector assembly.

32. The method of claim 31 wherein said tissue connector assembly is pulled with at least a portion of said tissue connector assembly positioned in said portions of material.

33. The method of claim 31 wherein said tissue connector assembly is pulled with at least a portion of said clip positioned in one of said portions of material.

34. The method of claim 30 including inserting a flexible member coupled to said clip through said portions of material, and at least one end of said tissue connector assembly is pulled to draw said materials together.

35. The method of claim 34 wherein said clip is pulled to draw said materials together.

36. The method of claim 30 wherein said tissue connector assembly is inserted into said multiple portions of material with a needle.

37. The method of claim 36 including simultaneously actuating closure of said clip and release of said needle therefrom.

38. The method of claim 36 including manipulating a portion of said tissue connector assembly to both actuate closure of said clip and release said needle from said clip.

39. A method for connecting a graft vessel to a target vessel in an anastomosis comprising:

inserting a tissue connector assembly through said graft and target vessels with said graft vessel being spaced from said target vessel and said tissue connector assembly having a first end extending from an exterior surface of said graft vessel and a second end extending from an exterior surface of said target vessel; and

pulling at least a portion of said tissue connector assembly to draw said graft vessel into contact with said target vessel.

40. The method of claim 39 further comprising inserting a second tissue connector assembly through said graft and target vessels prior to pulling at least a portion of said tissue connector assembly.

41. The tissue connector assembly of claim 1 including a second needle, said second needle being coupled to said surgical clip.

42. The tissue connector assembly of claim 41 including a second flexible member having a first portion coupled to said second needle and a second portion coupled to said clip.

43. The tissue connector assembly of claim 12 further comprising a coil surrounding said clip and a constraint extending from said clip, said clip having an enlarged portion and said coil being compressed between said constraint and enlarged portion.

44. A tissue connector assembly comprising a surgical fastener, which is adapted to assume a loop configuration, a first tissue piercing member and a second tissue piercing member, said surgical fastener having a first end portion and a second end portion, said first tissue piercing member being coupled to said first end portion and said second tissue piercing member being coupled to said second end portion.

45. The tissue connector assembly of claim 44 further including a flexible member, said flexible member having a first end portion coupled to said first tissue piercing member and a second end portion coupled to said first end portion of said fastener.

46. The tissue connector assembly of claim 45 further including a second flexible member, said second flexible member having a first end portion coupled to said second tissue piercing member and a second end portion coupled to said second end portion of said fastener.

47. The tissue connector assembly of claim 46 wherein said first flexible member comprises a suture.

48. The tissue connector assembly of claim 46 wherein each of said flexible members comprises a suture.

49. The tissue connector assembly of claim 46 wherein at least one of said flexible members comprises metal.

50. The tissue connector assembly of claim 45 wherein said flexible member comprises a suture.

51. The tissue connector assembly of claim 45 wherein said flexible member comprises metal.

52. The tissue connector assembly of claim 44 wherein at least one of said tissue piercing members comprises a needle.

53. The tissue connector assembly of claim 44 wherein each of said tissue piercing members comprises a needle.

54. The tissue connector assembly of claim 44 further including a coupling, said first tissue piercing member and said first end portion of said surgical fastener being coupled to said coupling.

55. The tissue connector assembly of claim 54 wherein said coupling comprises a tubular member having movable portions and said surgical fastener includes an enlarged portion adapted for receipt in said movable portions.

56. The tissue connector assembly of claim 55 wherein said enlarged portion is spherical.

57. The tissue connector assembly of claim 55 wherein said movable portions comprise a plurality of strands.

58. The tissue connector assembly of claim 57 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

59. The tissue connector assembly of claim 57 wherein said strands comprise wires.

60. The tissue connector assembly of claim 57 wherein said strands comprise cables.

61. The tissue connector assembly of claim 54 including a second coupling, said surgical fastener second end portion and second piercing member being coupled to said second coupling.

62. The tissue connector assembly of claim 61 wherein said surgical fastener includes an enlarged portion and said second coupling comprises a generally tubular member having movable portions adapted to receive at least a portion of said second portion.

63. The tissue connector assembly of claim 62 wherein said movable portions comprise a plurality of strands.

64. The tissue connector assembly of claim 62 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

65. The tissue connector assembly of claim 61 wherein said second coupling releases the coupling between said second piercing member and said surgical fastener in response to releasing said fastener first end portion coupling.

66. The tissue connector assembly of claim 61 further including a coil surrounding said surgical fastener and wherein said fastener includes first and second enlarged portions and said fastener first end portion coupling and said second coupling are adapted for receipt of said fastener first and second enlarged portions, respectively, said second coupling including members having portions that have a radially outward bias and extend within said coil when said coil is compressed against said second coupling.

67. The tissue connector assembly of claim 61 further including a flexible member and a coil, said flexible member having a portion coupled to said second tissue piercing member and a portion coupled to said second coupling, said coil surrounding said surgical fastener and being compressed against said second coupling, said fastener including an enlarged portion and said fastener first end portion coupling being adapted for receipt of said enlarged portion, said second coupling including a first member fixedly

secured to said fastener and a second member slidably coupled to said fastener, and said flexible member being compressed between said second coupling members when said coil is compressed against said slidably coupled member.

68. The tissue connector assembly of claim 61 wherein said fastener includes a groove and projection and said second coupling includes a member having a groove and projection and a sleeve slidably mounted thereon, said fastener groove and projection being configured to mate with said coupling member groove and projection.

69. The tissue connector assembly of claim 61 further including a flexible member having a portion coupled to said second tissue piercing member and a knotted portion, said second coupling including a tubular member having a bore, said knotted portion being in said bore and said bore having a portion with a diameter less than that of a section of said knotted portion.

70. The tissue connector assembly of claim 61 wherein said second coupling comprises an annular blade coupled to said second piercing member, said annular blade surrounding and being secured to a portion of said surgical fastener.

71. The tissue connector assembly of claim 44 wherein said surgical fastener comprises a surgical clip.

72. The tissue connector assembly of claim 71 wherein said surgical clip comprises a wire.

73. The tissue connector assembly of claim 72 further including a coil surrounding at least a portion of said wire and having confined ends.

74. The tissue connector of claim 72 wherein said wire comprises shape memory material.

75. The tissue connector assembly of claim 71 wherein said surgical clip has an open configuration and a closed configuration.

76. The tissue connector assembly of claim 75 wherein said surgical clip is in said closed configuration when in a relaxed state.

77. The tissue connector assembly of claim 75 wherein said surgical clip is generally U-shaped when in said open configuration.

78. The tissue connector assembly of claim 75 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

79. A tissue connector assembly comprising a surgical fastener having first and second end portions, a first tissue piercing member, a second tissue piercing member, and at least one flexible member having first and second end portions, said at least one flexible member first end portion being attached to said first tissue piercing member, said at least one flexible member second end portion being coupled to said first end portion of said surgical fastener, said second end portion of said surgical fastener being coupled to said second tissue piercing member.

80. The tissue connector assembly of claim 79 wherein said at least one flexible member comprises a suture.

81. The tissue connector assembly of claim 79 wherein said at least one flexible member comprises metal.

82. The tissue connector assembly of claim 79 further including a coupling, said flexible member and surgical fastener being secured to said coupling.

83. The tissue connector assembly of claim 82 wherein said coupling and flexible member have outer surfaces, said coupling and flexible member being configured to form a smooth, continuous transition there between along said outer surfaces.

84. The tissue connector assembly of claim 82 wherein said coupling and flexible member form an interface, at least a portion of each of said coupling and flexible member adjacent to said interface having the same cross-sectional shape and dimension.

85. The tissue connector assembly of claim 82 wherein said coupling and flexible member have essentially the same cross-sectional shape and dimension.

86. The tissue connector assembly of claim 82 wherein said surgical fastener is releasably coupled to said coupling.

87. The tissue connector assembly of claim 82 wherein said surgical fastener includes an enlarged portion and said coupling comprises a tubular member having movable portions adapted to receive at least a portion of said enlarged portion.

88. The tissue connector assembly of claim 87 wherein said enlarged portion is spherical.

89. The tissue connector assembly of claim 87 wherein said movable portions comprises a plurality of strands.

90. The tissue connector assembly of claim 89 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

91. The tissue connector assembly of claim 89 wherein said strands comprise wires.

92. The tissue connector assembly of claim 89 wherein said strands comprise cables.

93. The tissue connector assembly of claim 82 including a second coupling, said surgical fastener second end portion and second piercing member being coupled to said second coupling.

94. The tissue connector assembly of claim 93 wherein said surgical fastener includes a second enlarged portion and said second coupling comprises a generally tubular member having movable portions adapted to receive at least a portion of said enlarged portion.

95. The tissue connector assembly of claim 94 wherein said movable portions comprise a plurality of strands.

96. The tissue connector assembly of claim 94 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

97. The tissue connector assembly of claim 93 wherein said second coupling releases the coupling between said second piercing member and said surgical fastener in response to releasing said fastener first end portion coupling.

98. The tissue connector assembly of claim 93 further including a coil surrounding said surgical fastener and wherein said fastener includes first and second enlarged portions and said fastener first end portion coupling and said second coupling are adapted for receipt of said fastener first and second enlarged portions, respectively, said second coupling including members that are biased radially inward with portions extending within said coil when said coil is compressed against said second coupling.

99. The tissue connector assembly of claim 93 further including a second flexible member and a coil, said second flexible member having a portion coupled to said second tissue piercing member and a portion coupled to said second coupling, said coil surrounding said surgical fastener and being compressed against said second coupling, said fastener including an enlarged portion and said fastener first end portion coupling being adapted for receipt of said enlarged portion, said second coupling including a first member fixedly secured to said fastener and a second member slidably coupled to said fastener, and said flexible member being compressed between said second coupling members when said coil is compressed against said slidably coupled member.

100. The tissue connector assembly of claim 93 wherein said fastener includes a groove and projection and said second coupling includes a member having a groove and projection and a sleeve slidably mounted thereon, said fastener groove and projection being configured to mate with said coupling member groove and projection.

101. The tissue connector assembly of claim 93 further including a second flexible member having a portion coupled to said second tissue piercing member and a knotted portion, said second coupling including a tubular member having a bore, said knotted portion being in said bore and said bore having a portion with a diameter less than that of a section of said knotted portion.

102. The tissue connector assembly of claim 93 wherein said second coupling comprises an annular blade coupled to said second piercing member, said annular blade surrounding and being secured to a portion of said surgical fastener.

103. The tissue connector assembly of claim 79 wherein said surgical fastener comprises a surgical clip.

104. The tissue connector assembly of claim 103 wherein said surgical clip comprises a wire.

105. The tissue connector assembly of claim 104 further including a coil surrounding at least a portion of said wire and having confined ends.

106. The tissue connector of claim 104 wherein said wire comprises shape memory material.

107. The tissue connector assembly of claim 103 wherein said surgical clip has an open configuration and a closed configuration.

108. The tissue connector assembly of claim 107 wherein said surgical clip is in said closed configuration when in a relaxed state.

109. The tissue connector assembly of claim 107 wherein said surgical clip is generally U-shaped when in said open configuration.

110. The tissue connector assembly of claim 107 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

111. A tissue connector assembly comprising two needles, a surgical clip and a flexible member having a portion releaseably coupled to said surgical clip and a portion coupled to one of said needles, the other one of said needles being coupled to said surgical clip.

112. The tissue connector assembly of claim 111 further comprising a second flexible member having a portion releaseably coupled to said surgical clip and a portion coupled to said other one of said needles.

113. Tissue connector apparatus comprising a wire, a tissue piercing member, a generally tubular member having first and second end portions and surrounding said wire and a coupling, said piercing member being coupled to said coupling and said coupling including members having portions that have a radially outward bias and extend within said tubular member second end portion, said tubular member second end portion being releasably constrained.

114. The apparatus of claim 113 wherein said generally tubular member is a coil.

115. Tissue connector apparatus comprising a surgical fastener, a tissue piercing member, a flexible member, a coupling, and a coil, said flexible member having a portion coupled to said piercing member and a portion coupled to said coupling, said coil surrounding said surgical fastener and being compressed against said coupling, said coupling including a first member fixedly secured to said fastener and a second member slidably coupled to said fastener, and said flexible member being positioned between said coupling members, and said coil surrounding said surgical fastener and having one end releaseably constrained and the other end compressed against said slidably coupled member.

116. Tissue connector apparatus comprising a surgical fastener, tissue piercing member and a coupling said fastener including a groove and projection and said coupling including a member having a groove and projection and a sleeve slidably mounted thereon,

said fastener groove and projection being configured to mate with said coupling member groove and projection.

117. Tissue connector apparatus comprising a surgical fastener, a tissue piercing member, a flexible member having a portion coupled to said tissue piercing member and a knotted portion, and a tubular member having a bore, said fastener being coupled to said tubular member and said knotted portion being in said bore, said bore having a portion with a diameter less than that of a section of said knotted portion.

118. Tissue connector apparatus comprising a surgical fastener, an annular blade and a tissue piercing member, said tissue piercing member being coupled to said annular blade, and said annular blade surrounding and being secured to a portion of said surgical fastener.

119. A method of decoupling multiple tissue piercing members from a surgical fastener comprising actuating release of multiple piercing members, which are coupled to a surgical fastener, essentially simultaneously.

120. A method of decoupling multiple tissue piercing members from a surgical fastener comprising releasing multiple tissue piercing members, which are coupled to a surgical fastener, with a single release actuator.

121. A method of decoupling multiple tissue piercing members from a surgical fastener including simultaneously actuating release of multiple needles from a surgical fastener.

122. The method of setting a tissue connector assembly including a surgical fastener and multiple tissue piercing members coupled thereto comprising manipulating a single portion of the tissue connector assembly to both release the tissue piercing members from the fastener and actuate closure of the fastener.

123. A method of securing portions of material together, at least one of which comprises tissue, the method comprising placing at least a portion of a first piercing member, having a surgical fastener coupled thereto, in a vessel lumen, placing at least a portion of a second piercing member, which also is coupled to the surgical fastener and where at least one of the piercing members is coupled to the surgical fastener with a flexible member, in a tubular graft, passing the first piercing member through the wall of the vessel from an interior surface thereof, passing the second piercing member through the wall of the tubular graft from an interior surface thereof, and positioning the fastener with one portion thereof extending through said vessel wall and another portion extending through said graft wall.

124. The method of claim 123 wherein the flexible member is selected to be a suture.

125. The method of claim 123 wherein all of the at least one flexible member and the piercing members are removed from the fastener.124. The method of claim 80 wherein the flexible member is selected to be a suture.

126. Surgical apparatus comprising an elongated flexible tubular member.

127. The apparatus of claim 126 wherein said flexible tubular member is a suture.

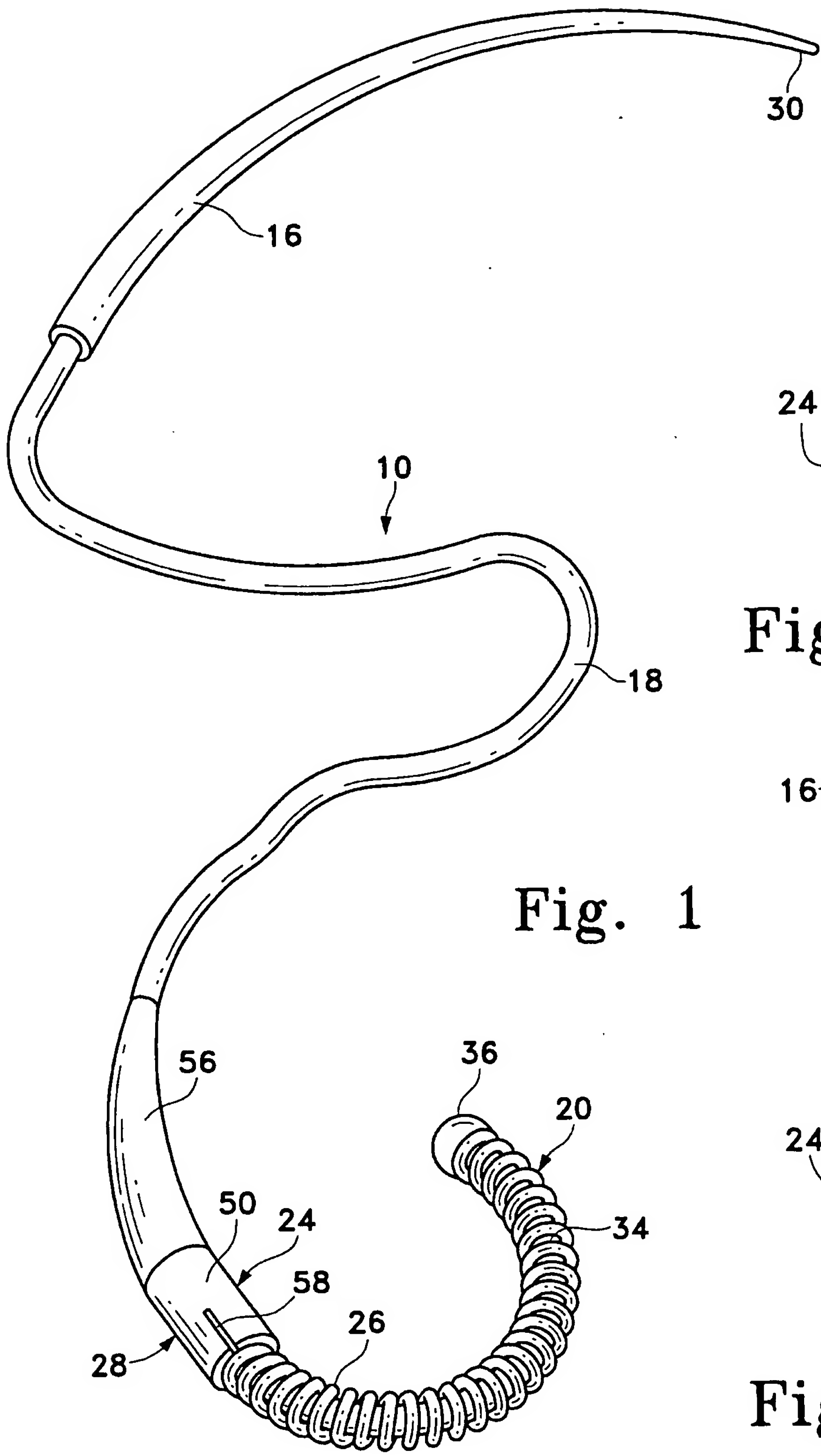


Fig. 1

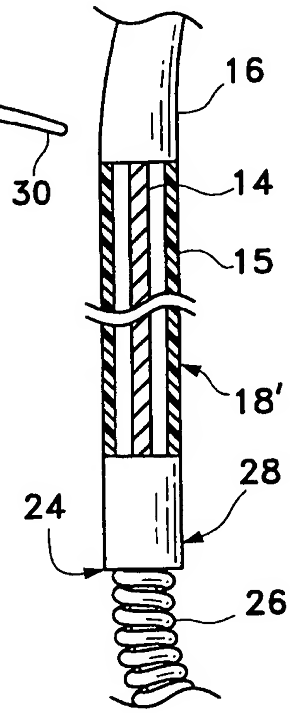


Fig. 1A

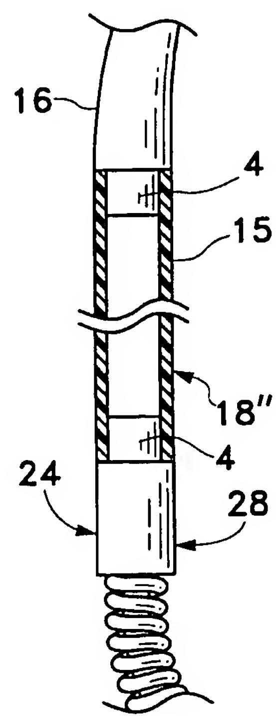


Fig. 1B

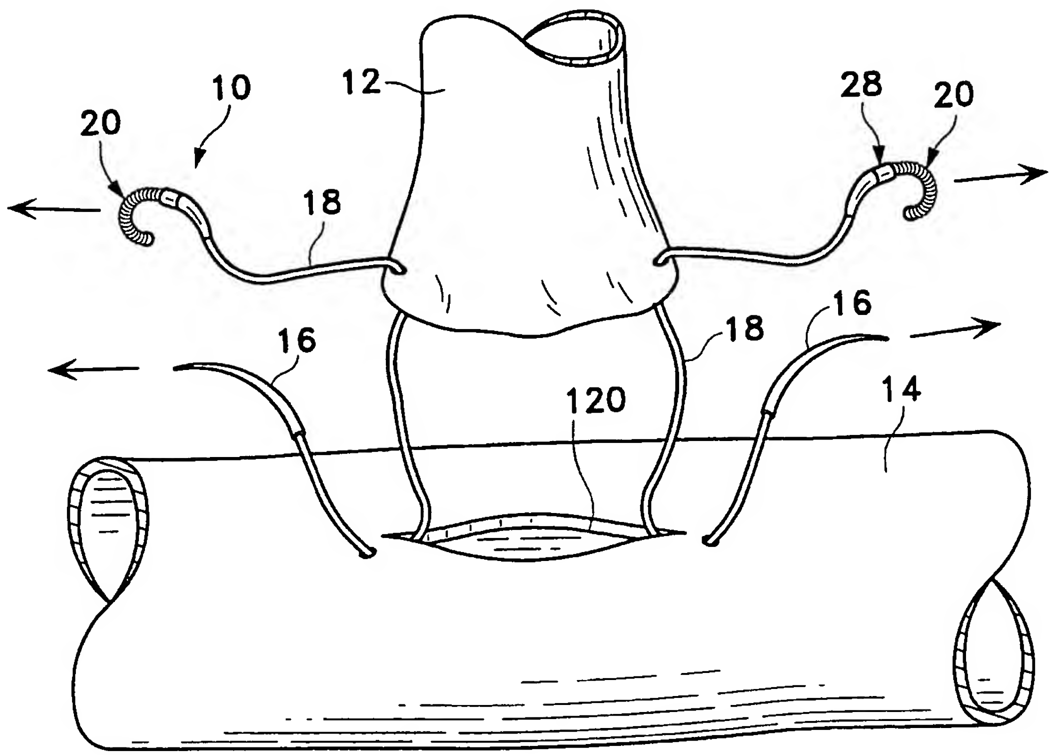


FIG. 2A

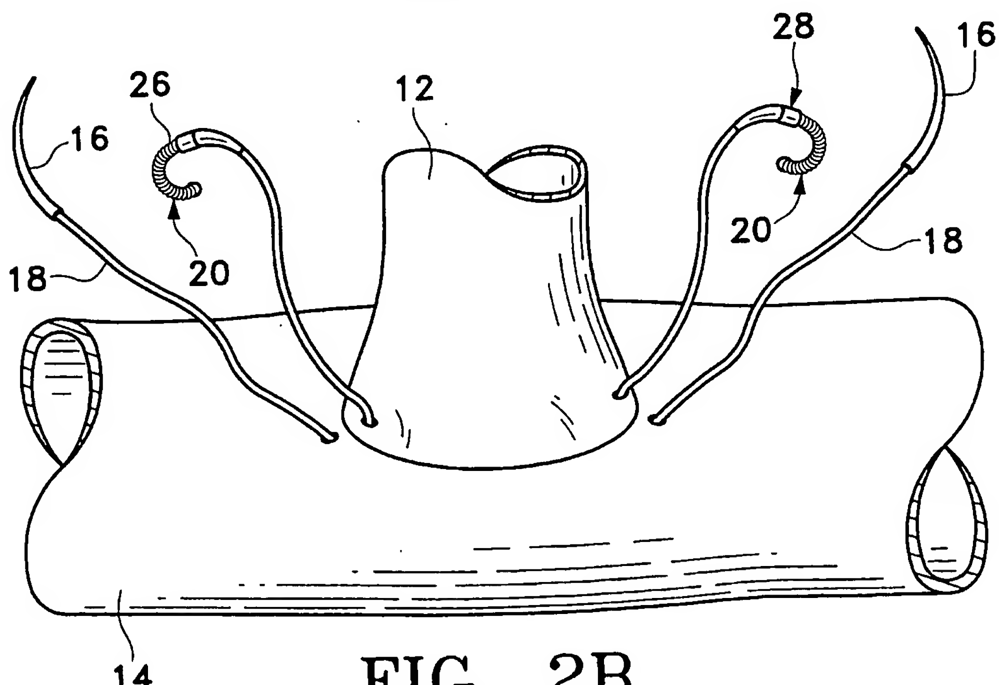


FIG. 2B

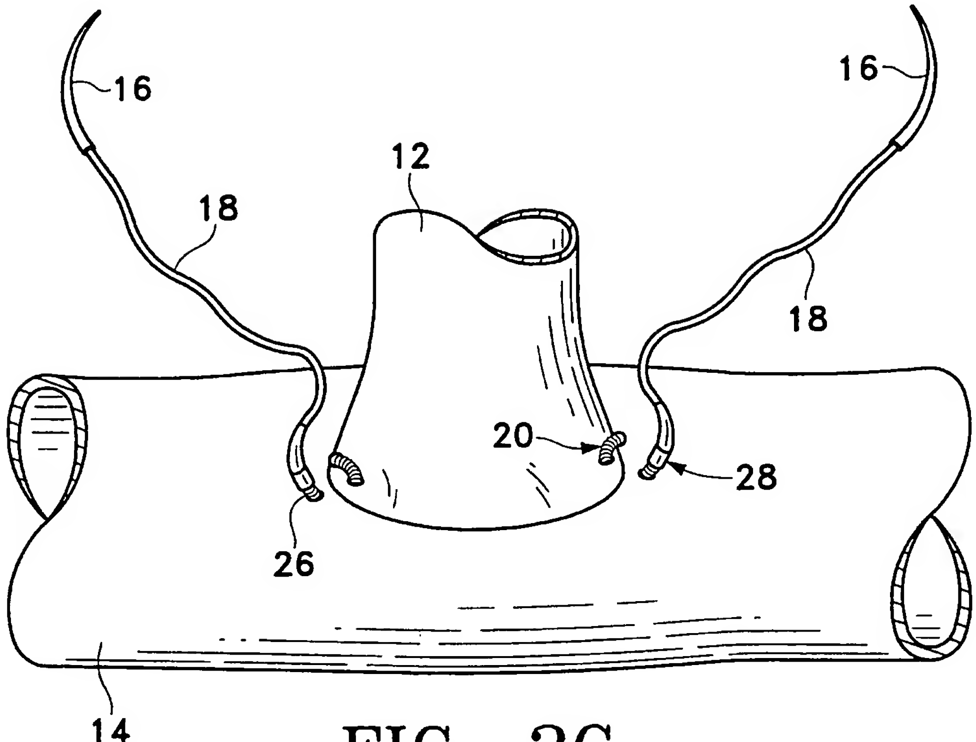


FIG. 2C

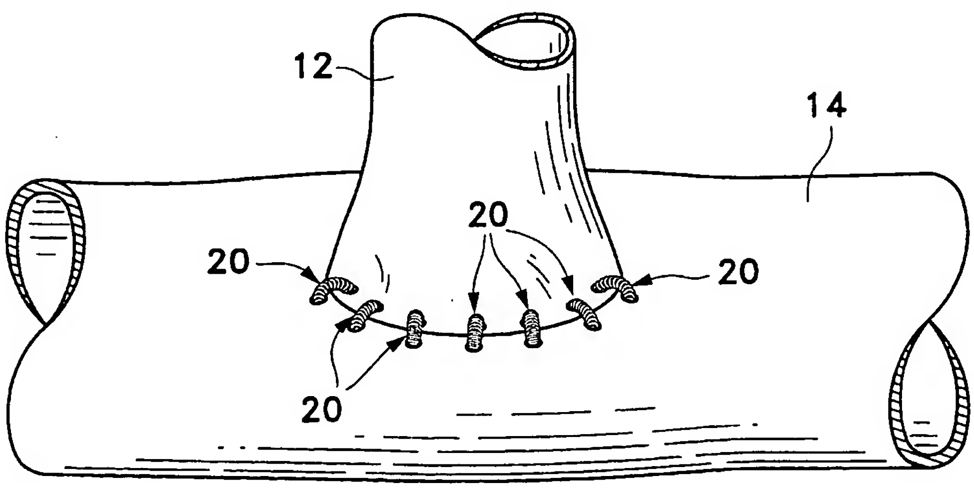


FIG. 2D

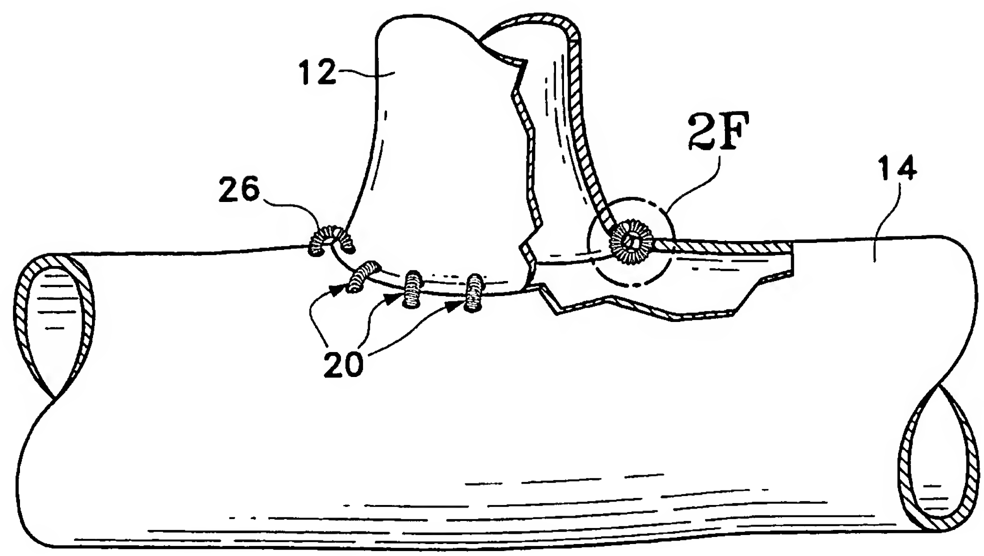


Fig. 2E

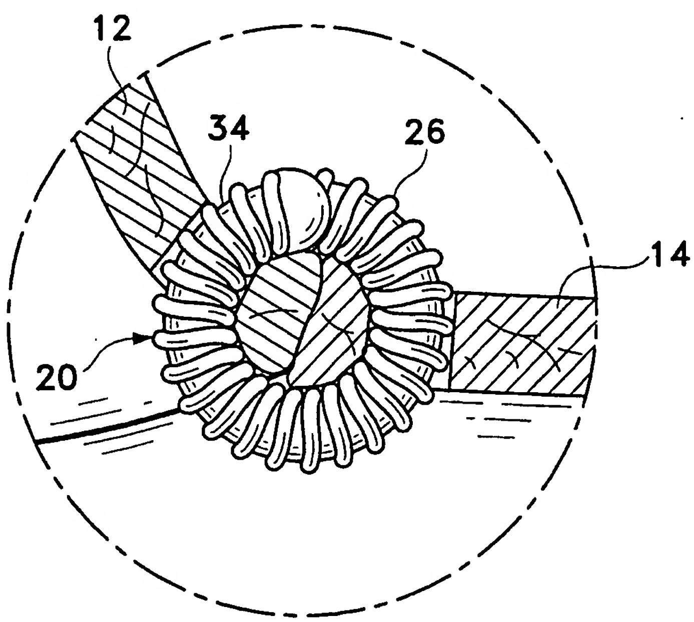


Fig. 2F

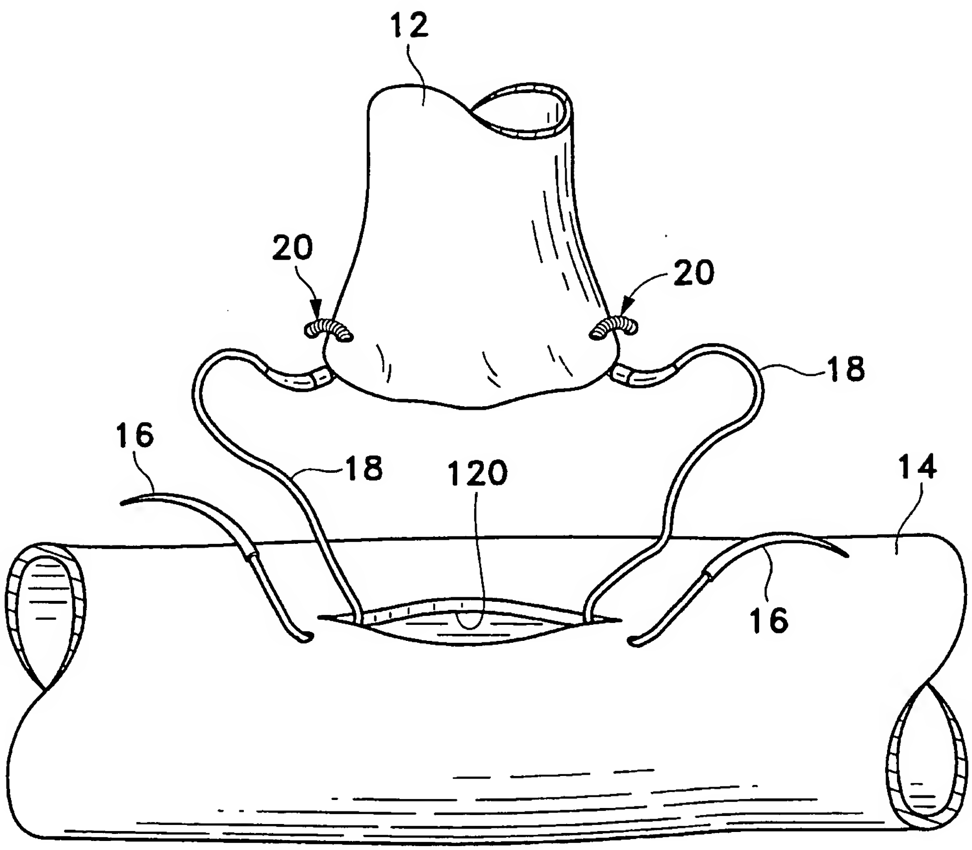


FIG. 2G

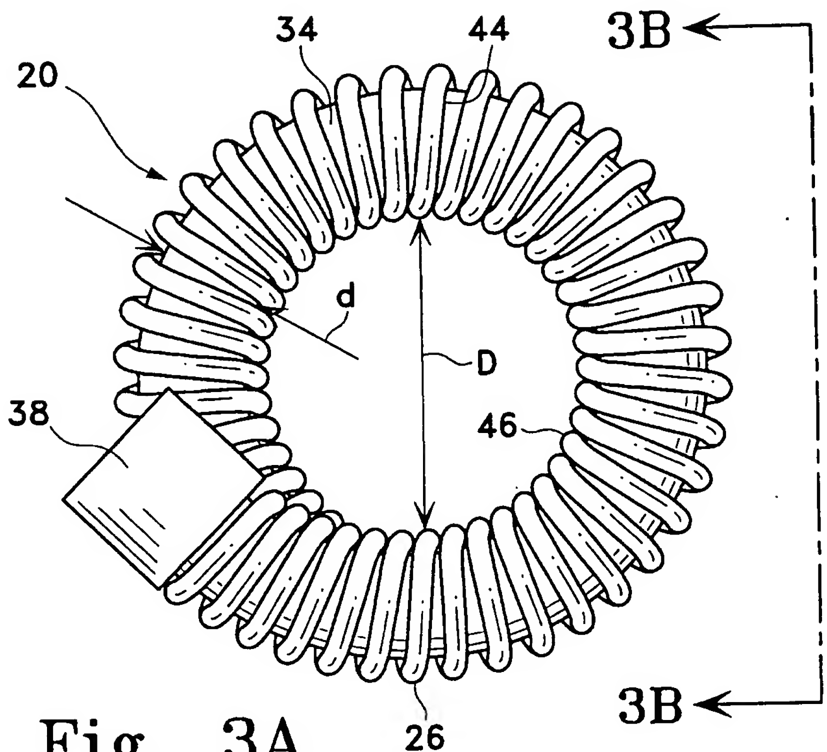


Fig. 3A

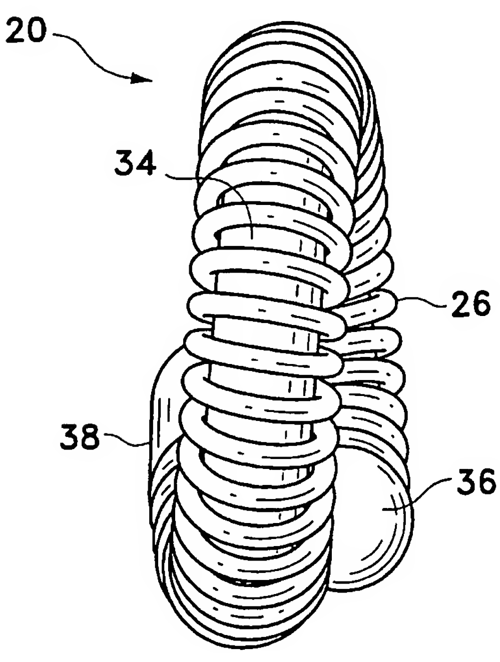


Fig. 3B

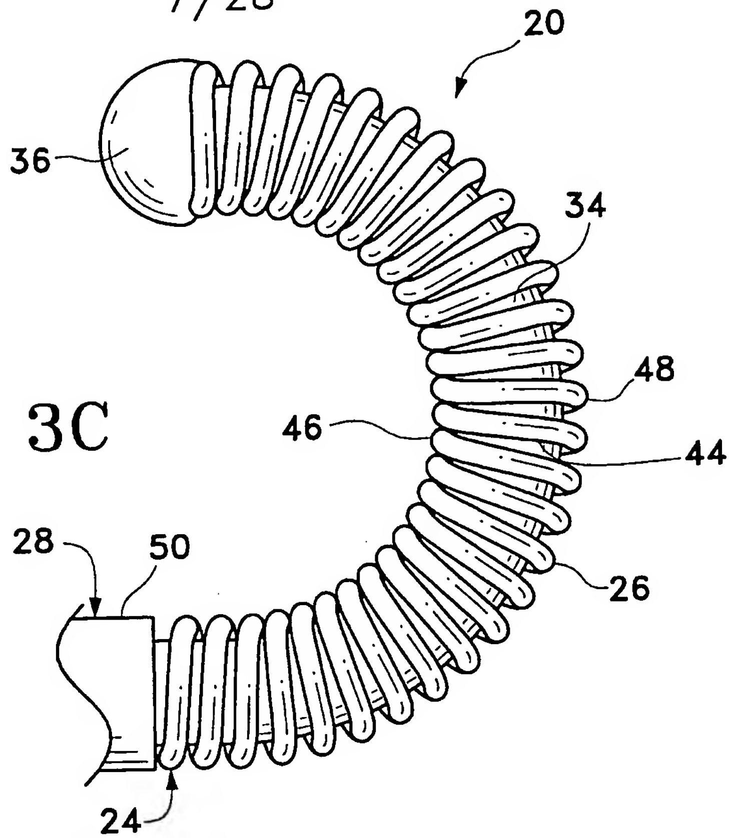


Fig. 3C

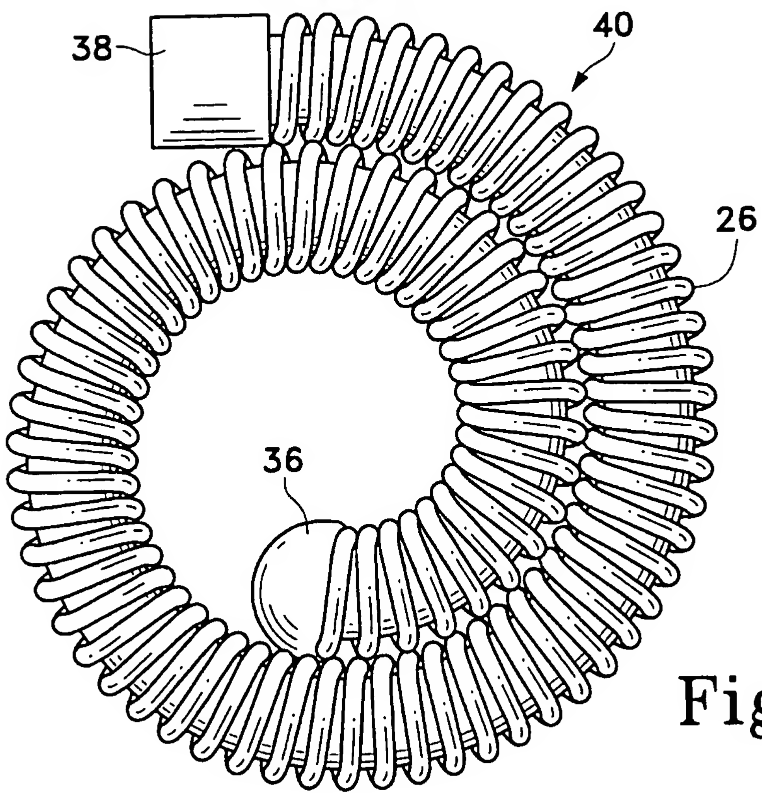


Fig. 4

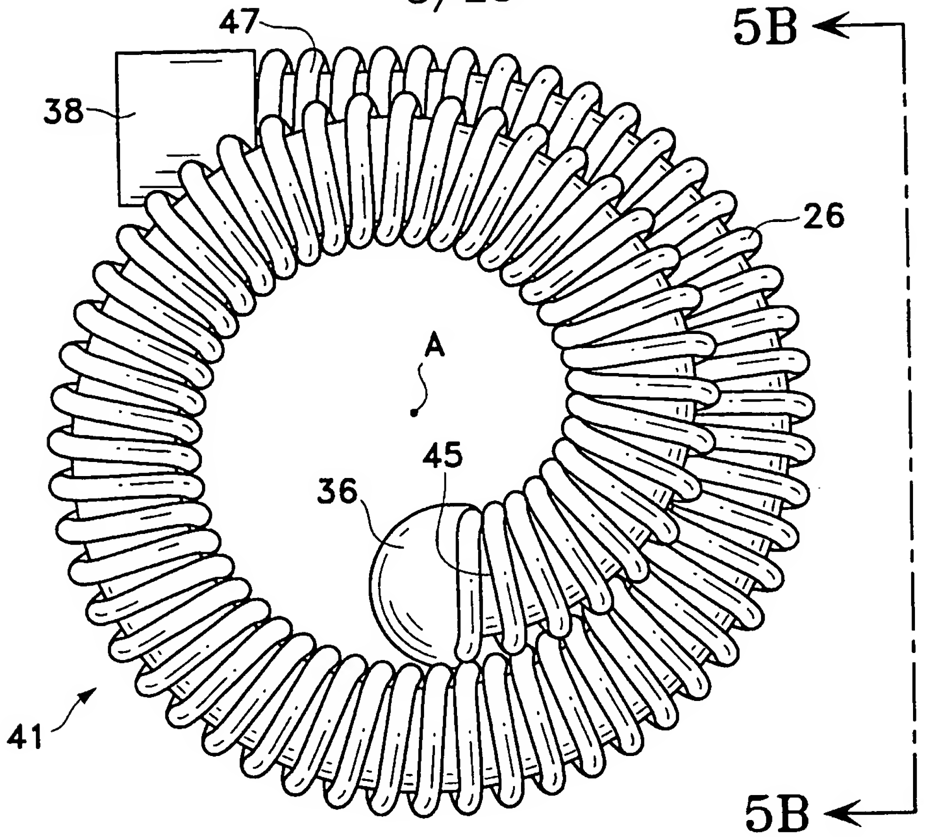


Fig. 5A

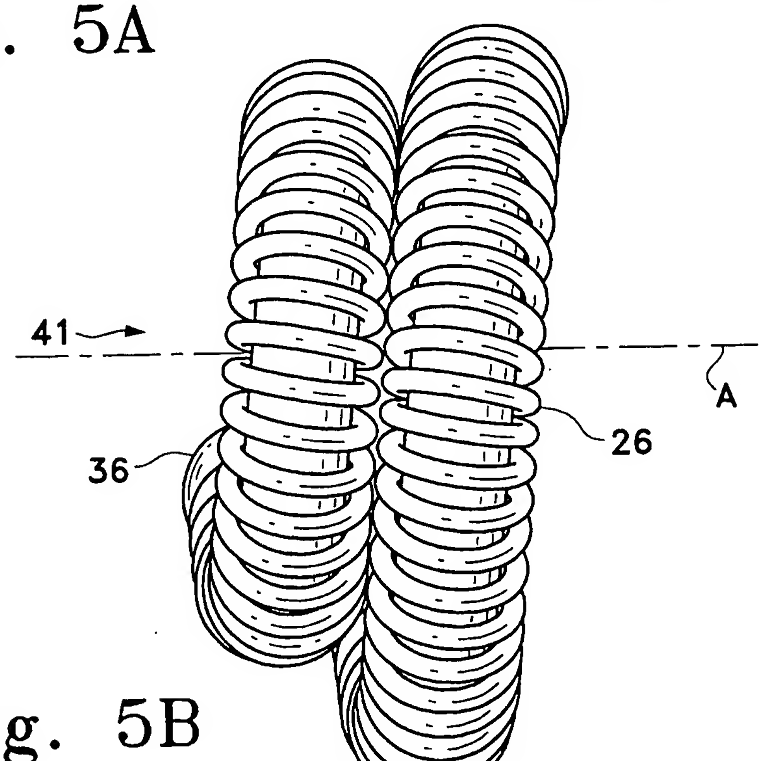


Fig. 5B

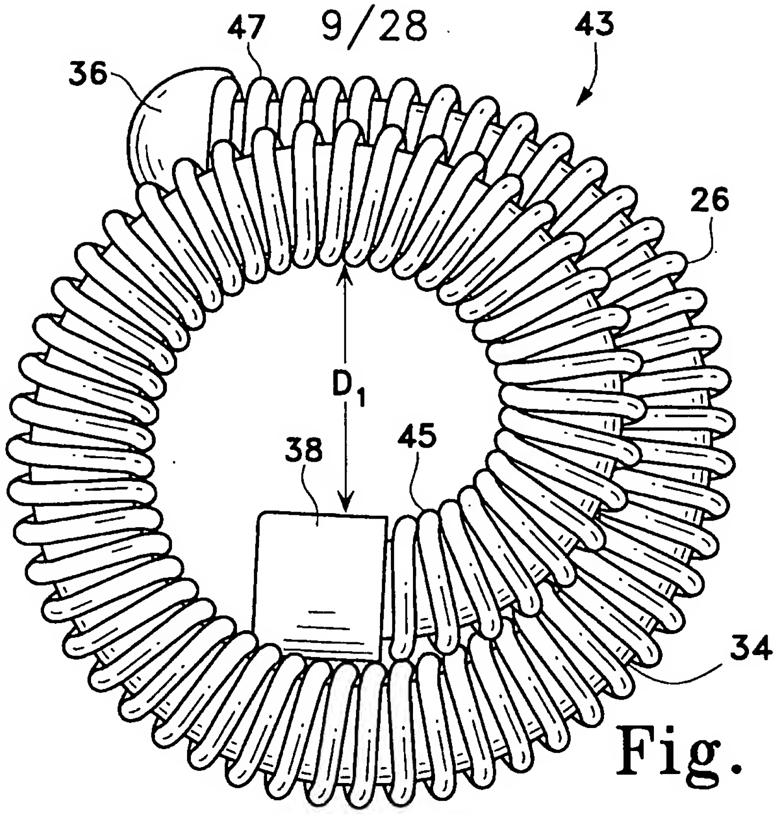


Fig. 6A

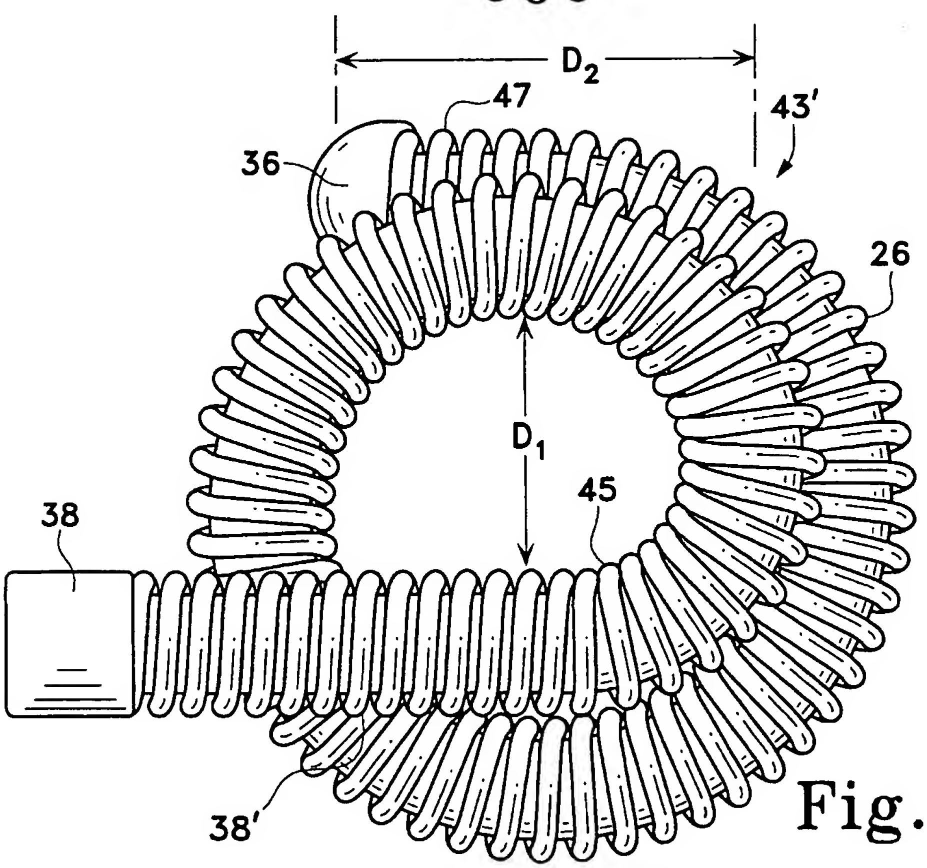


Fig. 6B

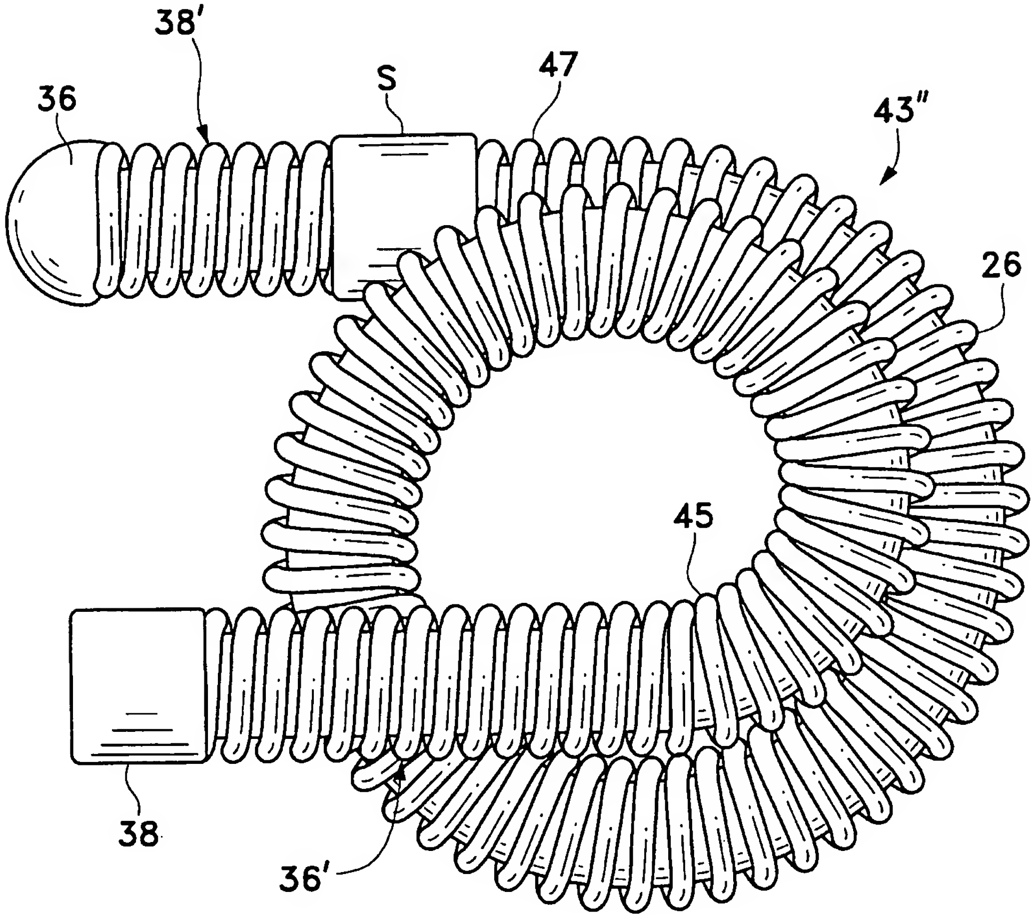


Fig. 6C

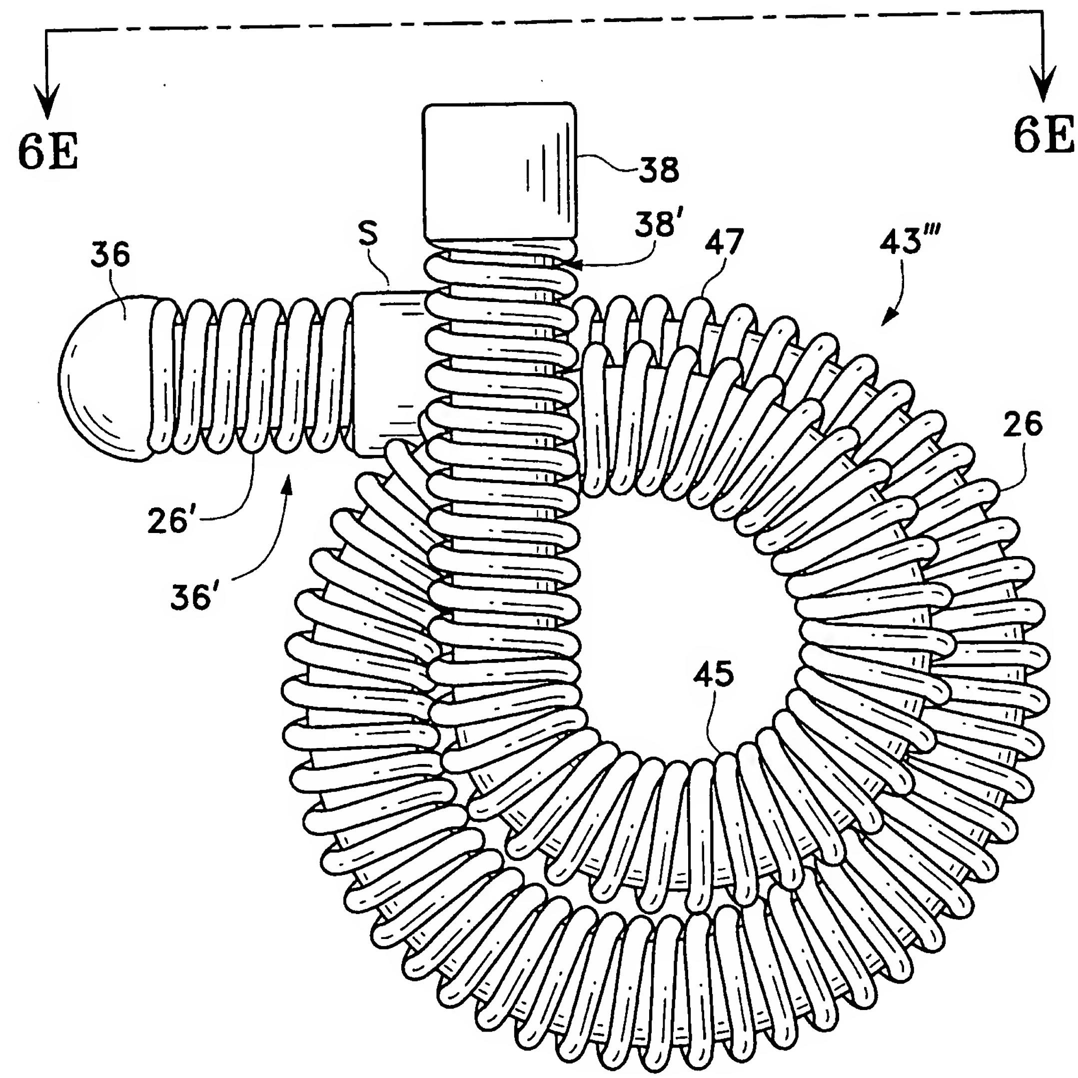


Fig. 6D

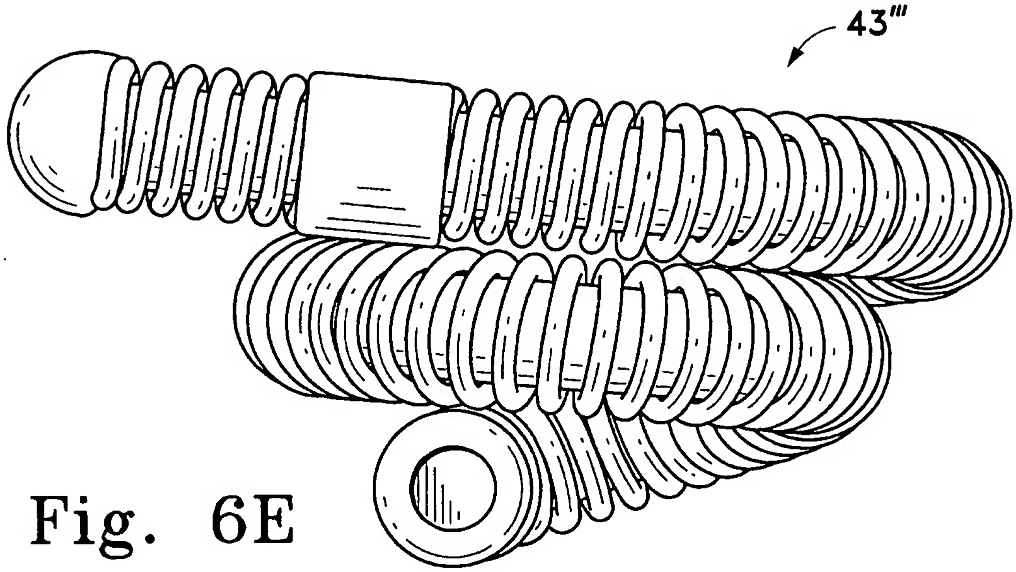


Fig. 6E

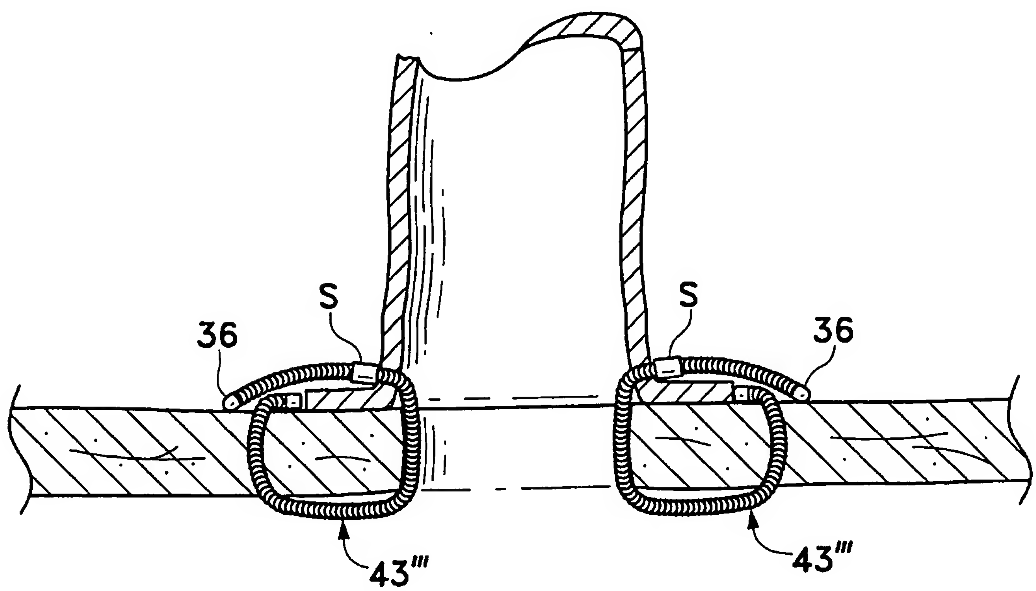


Fig. 6F

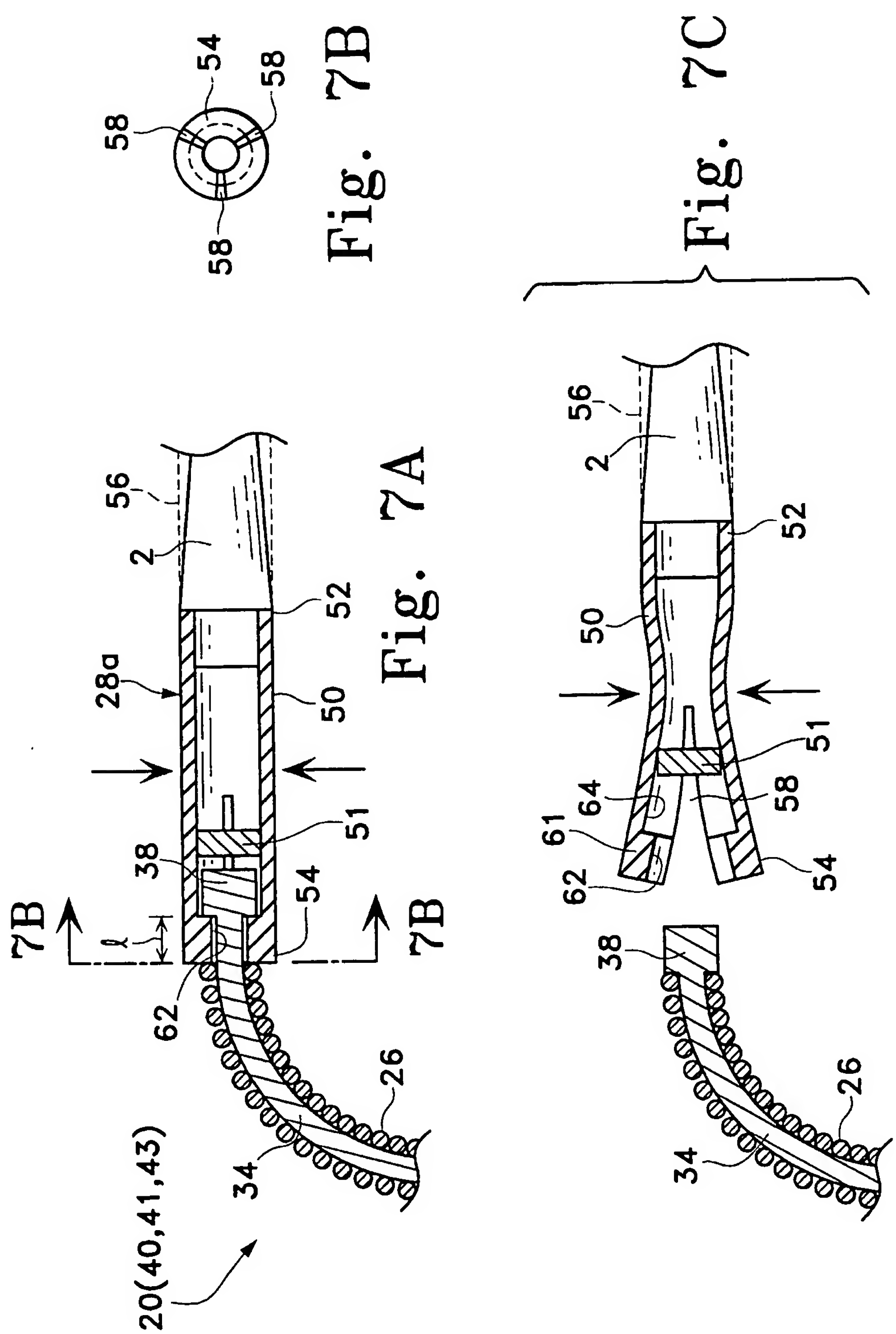


Fig. 7B

Fig. 7A

Fig. 7C

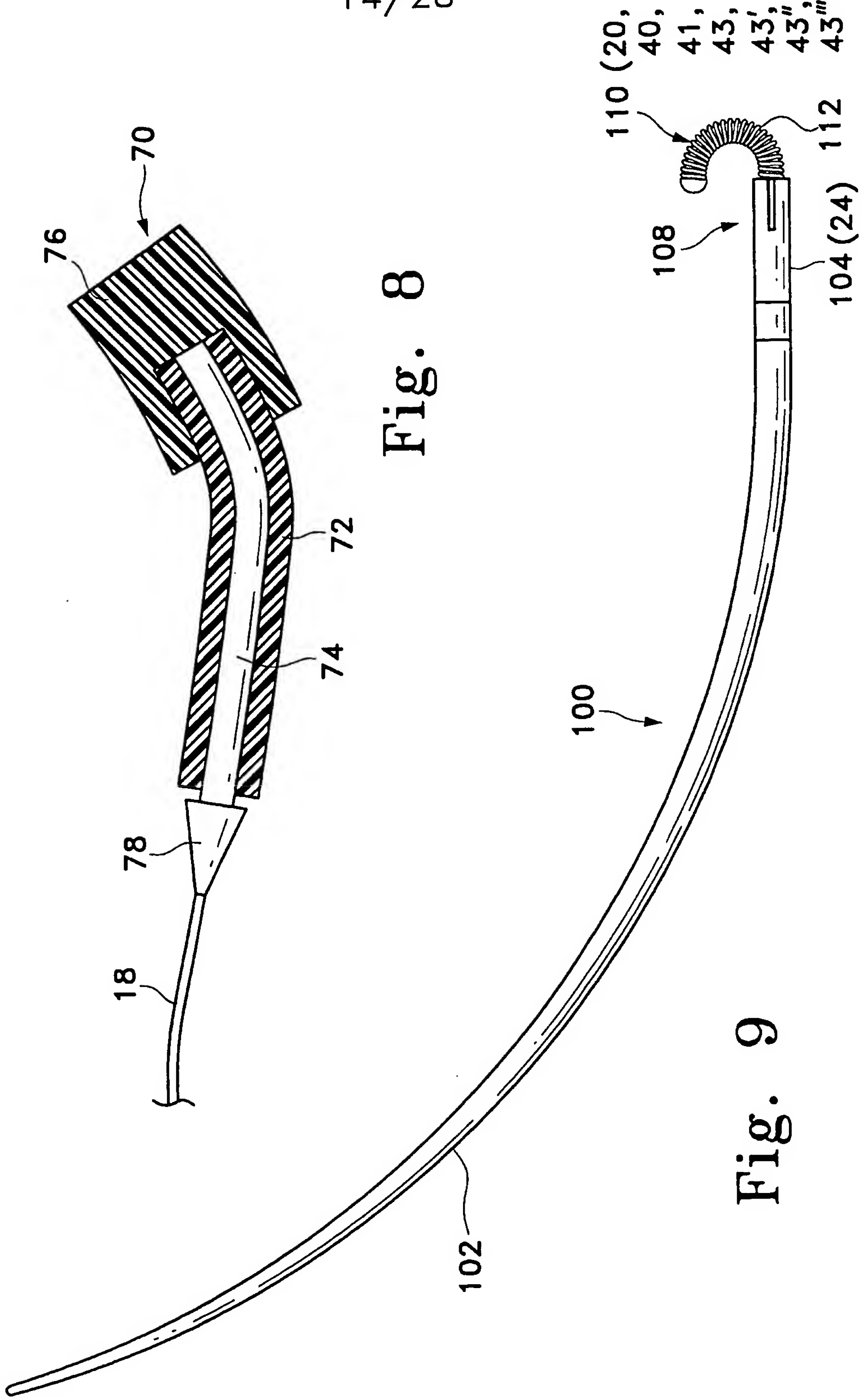


Fig. 8

Fig. 9

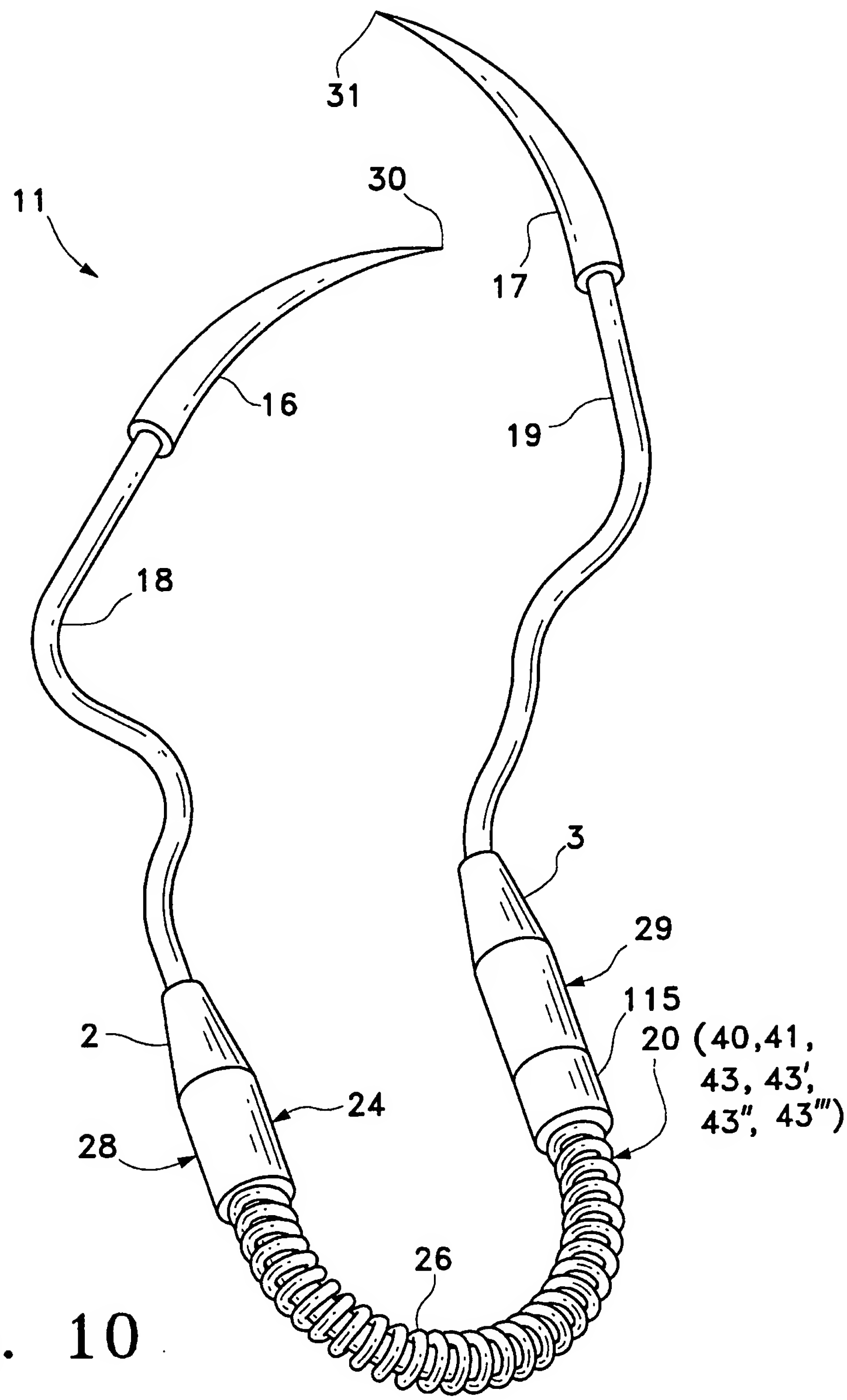


Fig. 10

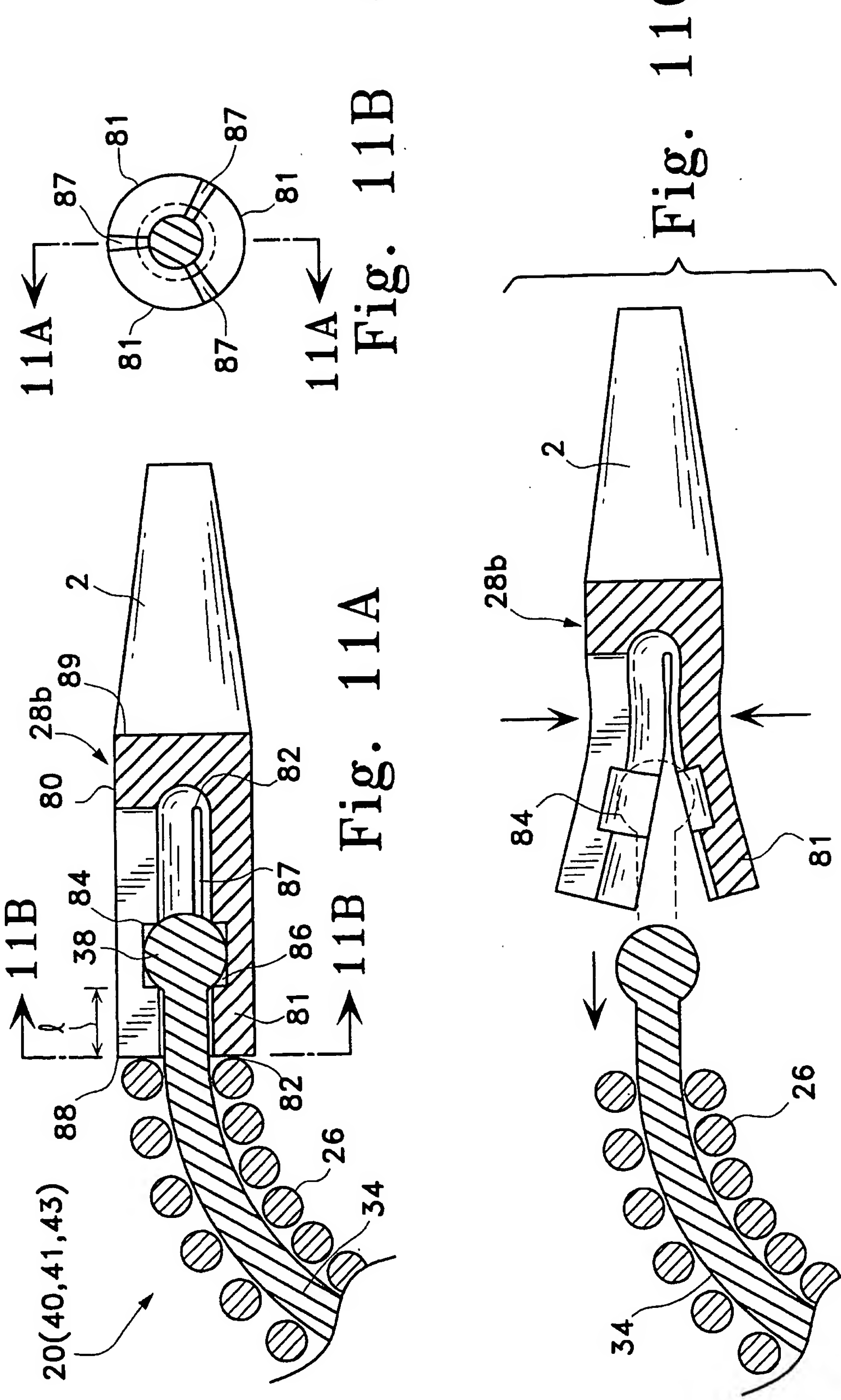


Fig. 11B

Fig. 11A

Fig. 11C

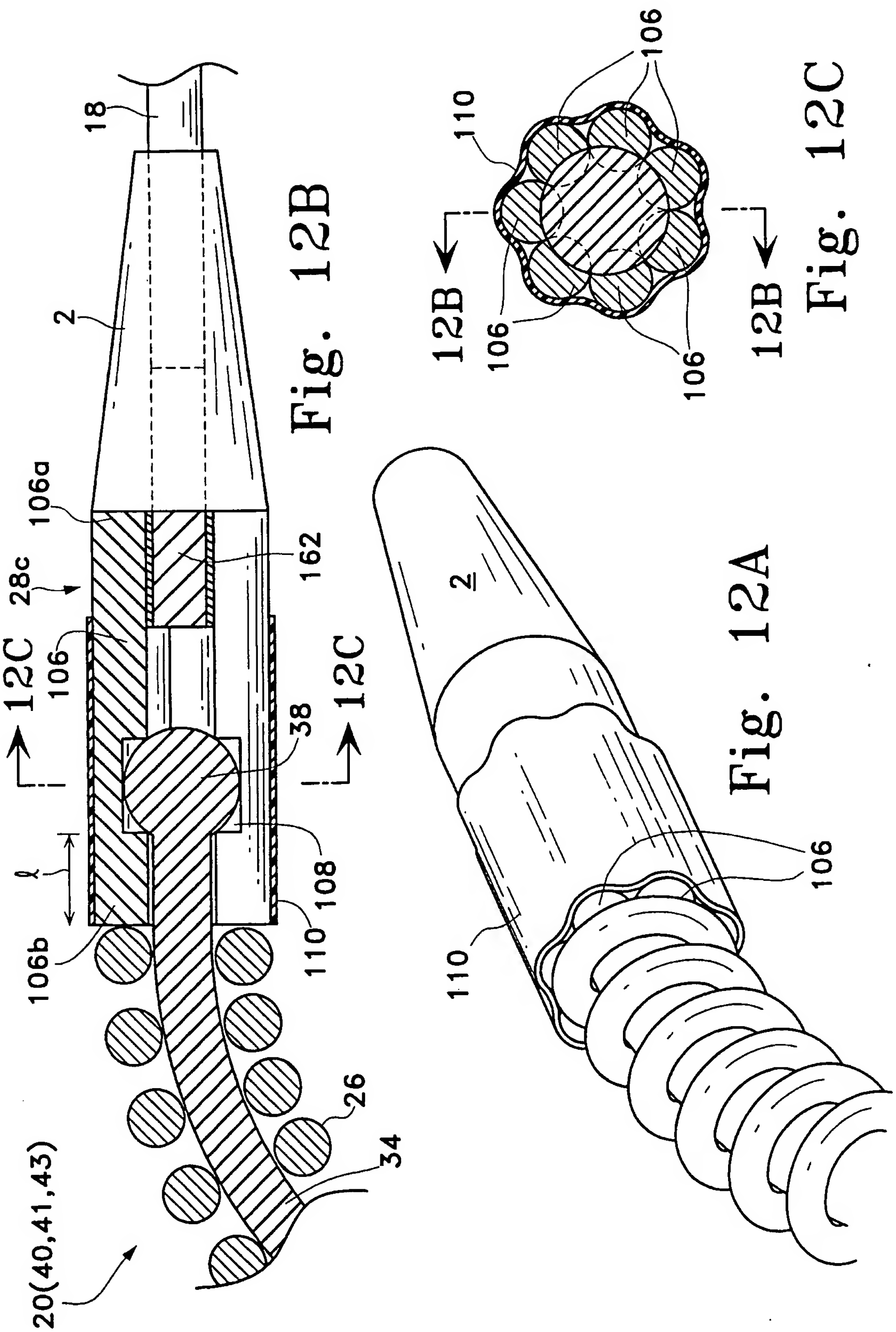


Fig. 12B

Fig. 12C

Fig. 12A

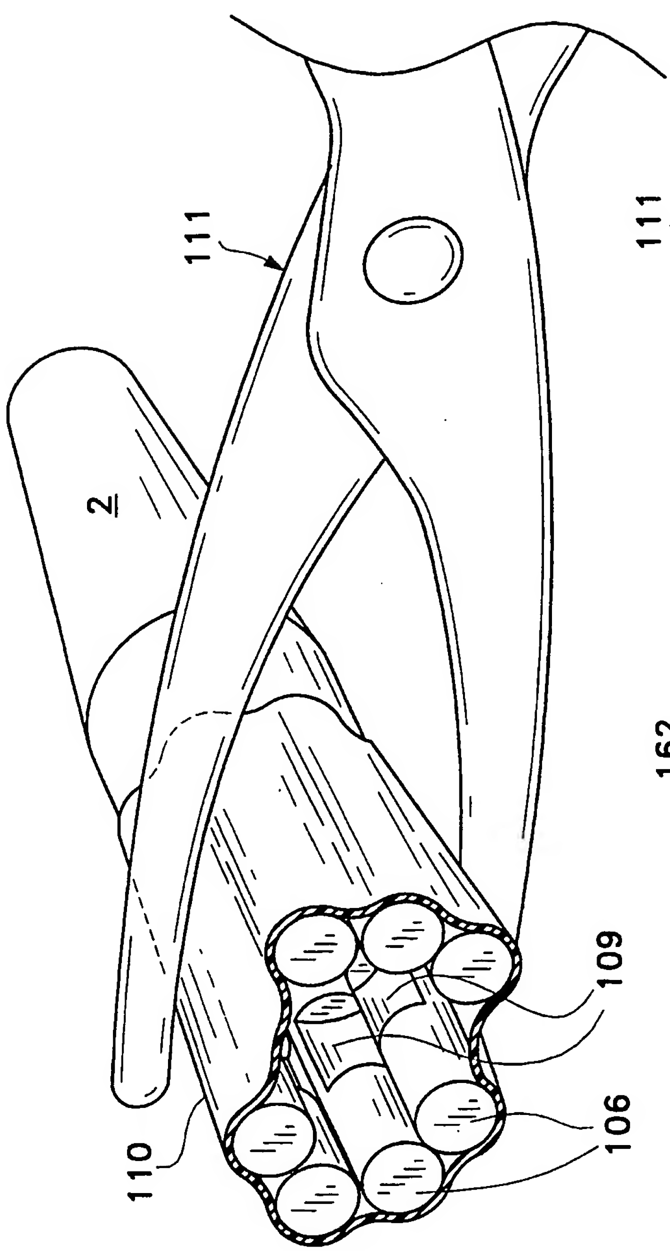


Fig. 12D

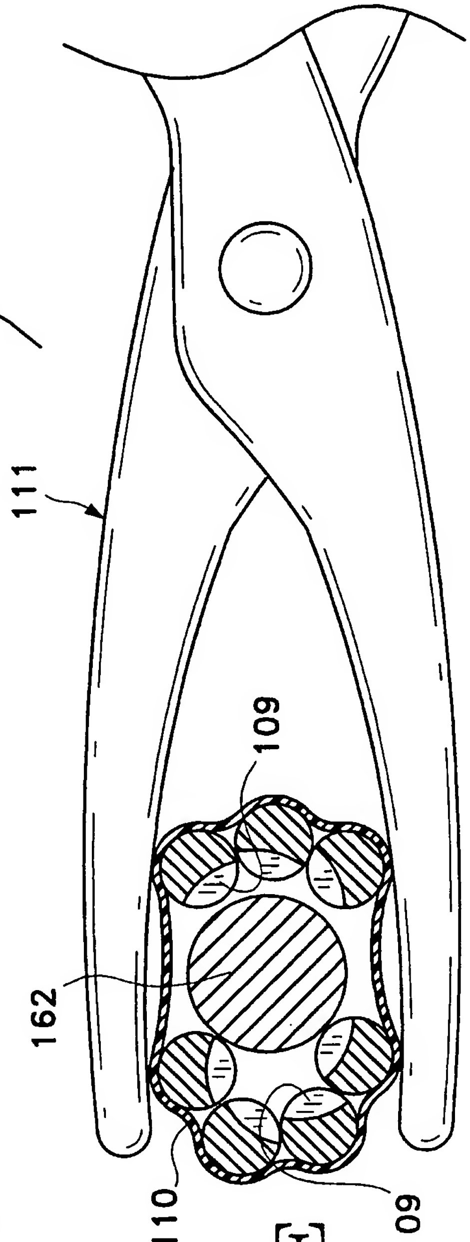


Fig. 12E

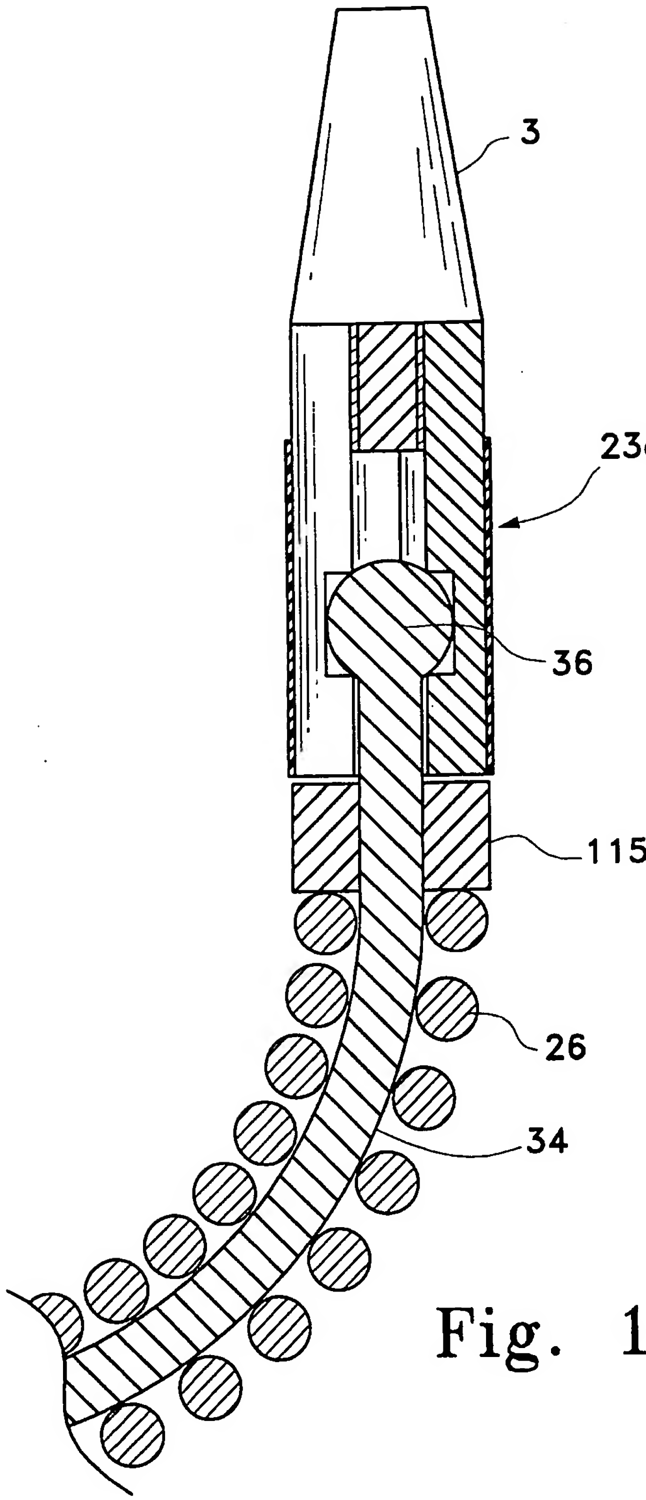


Fig. 12F

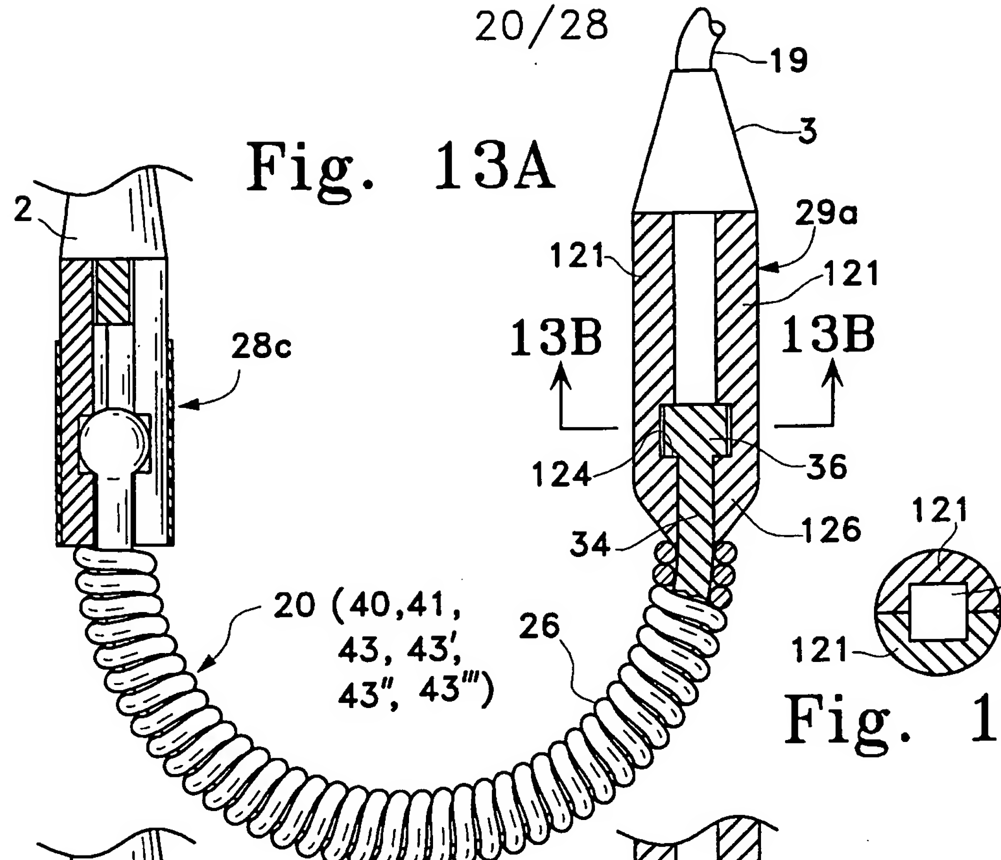
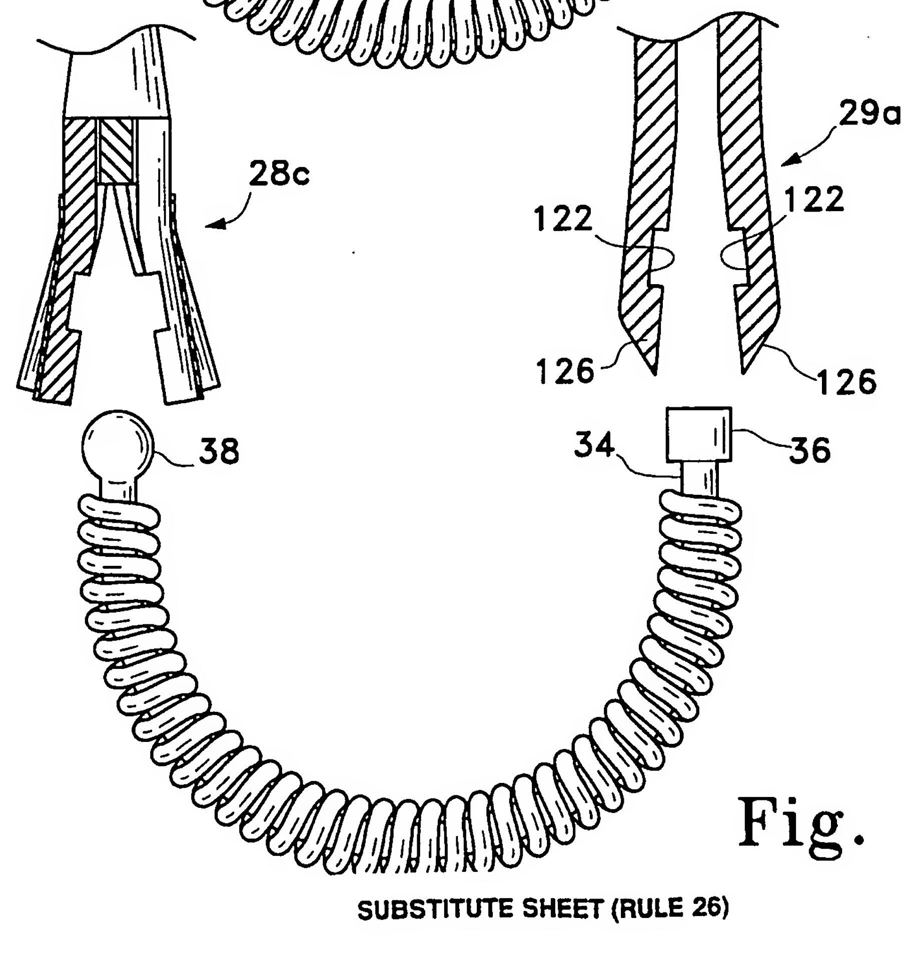


Fig. 13A

Fig. 13B



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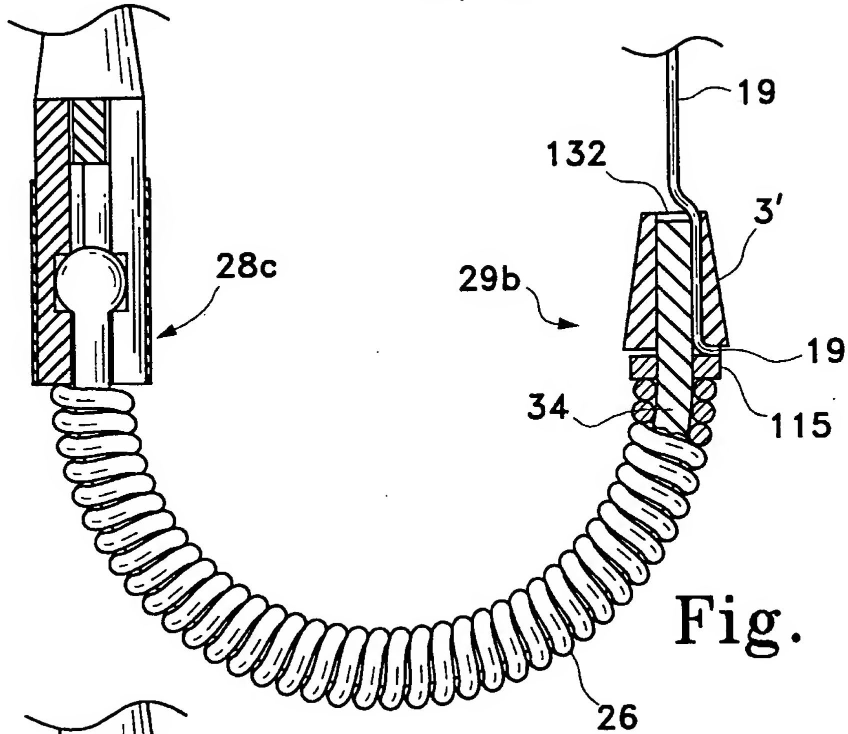


Fig. 13D

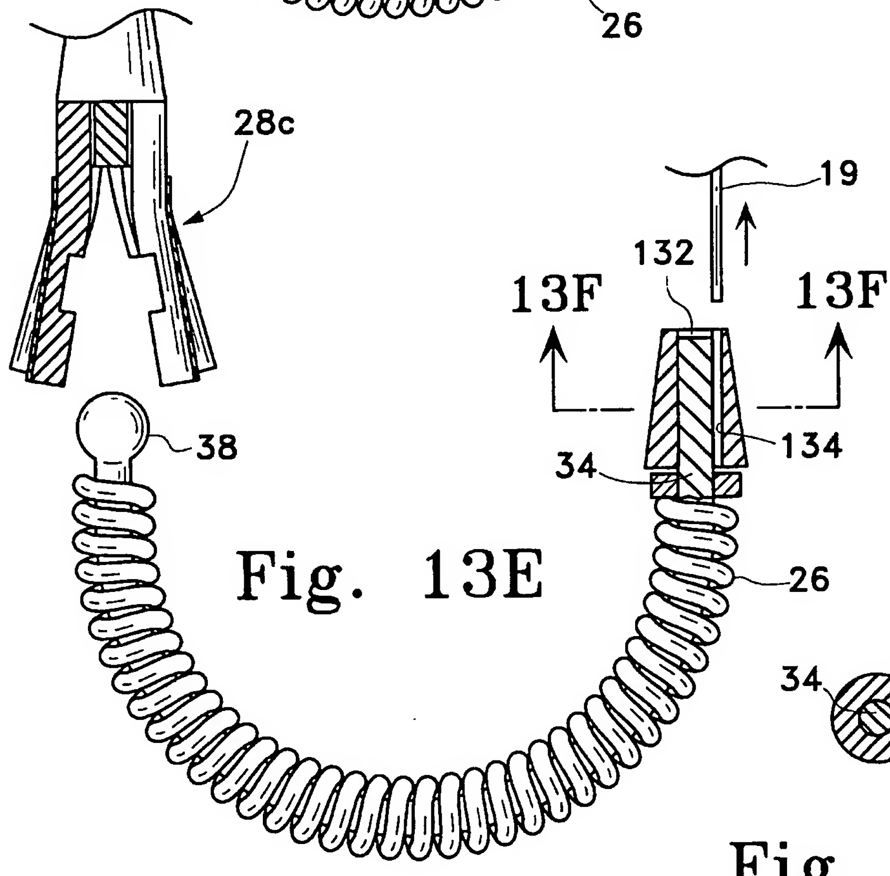


Fig. 13E

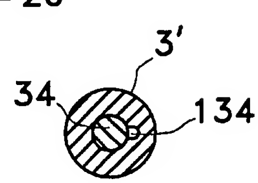


Fig. 13F

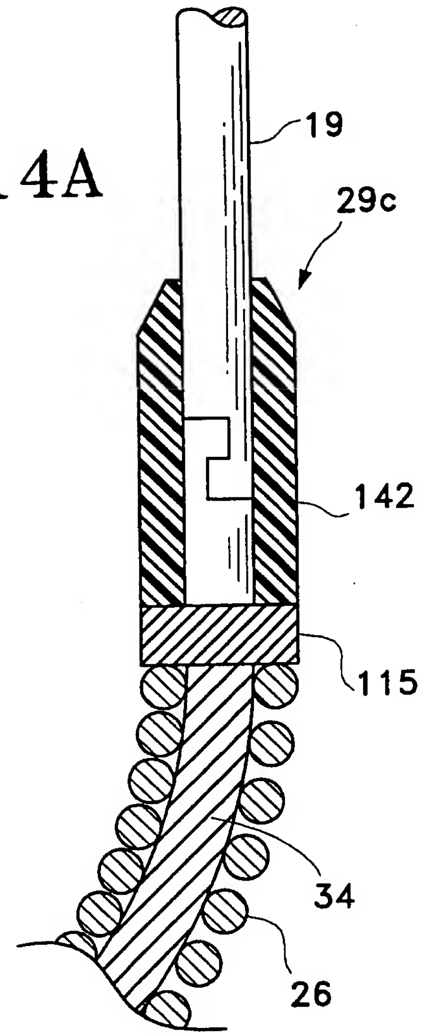


Fig. 14A

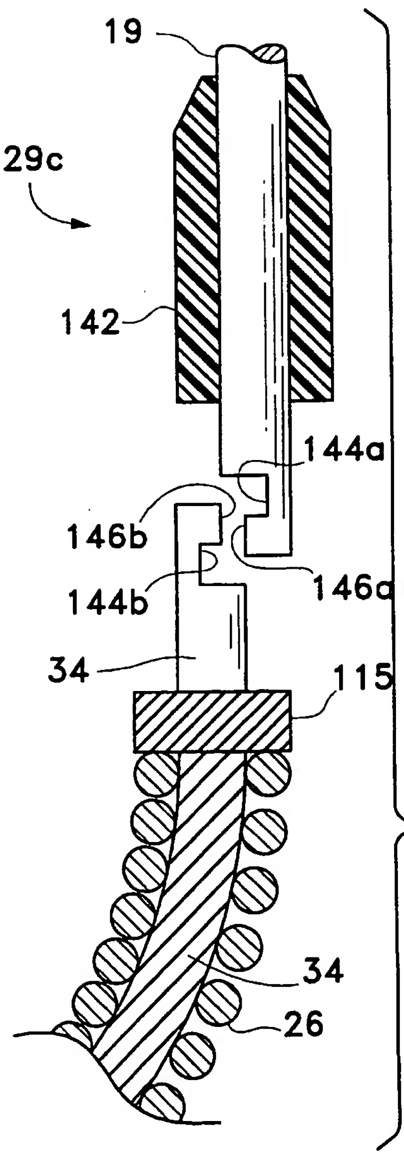
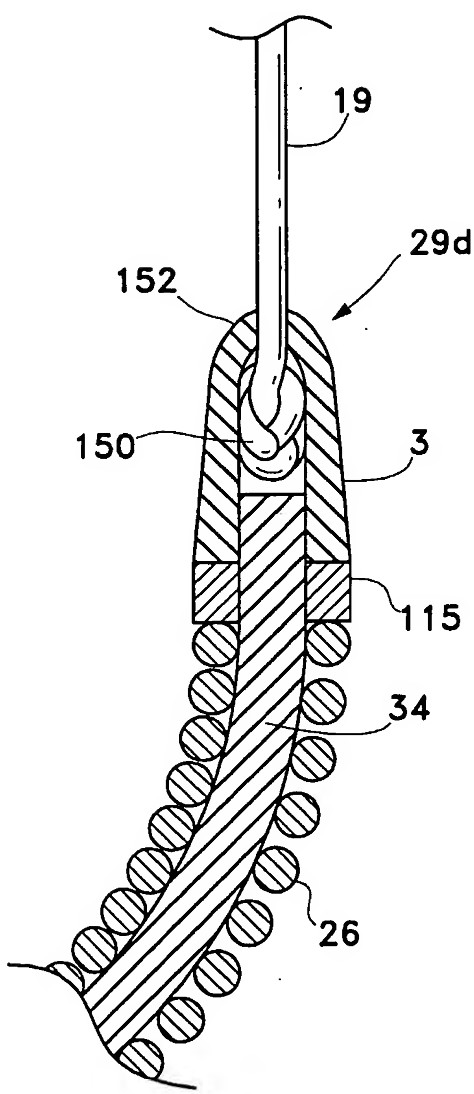


Fig. 14B



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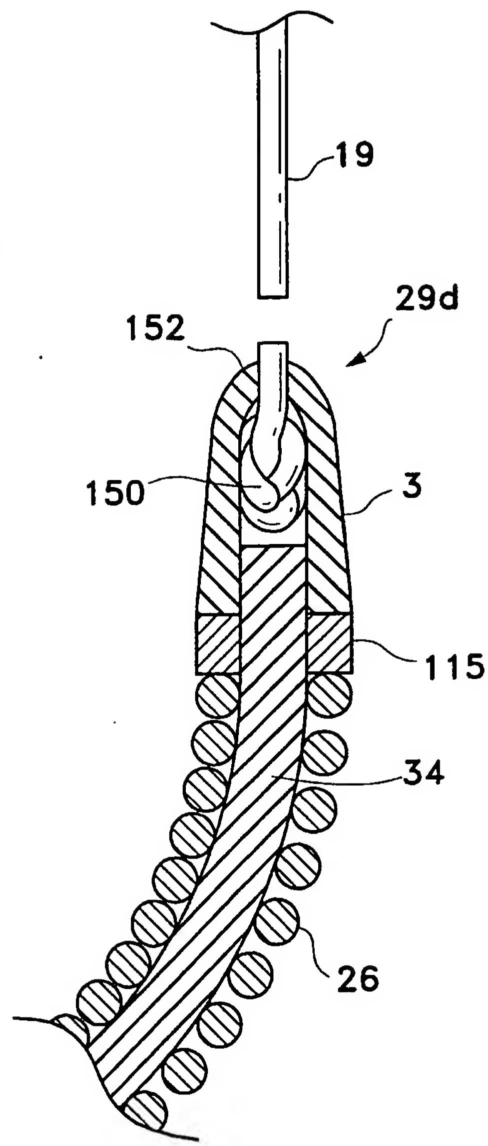

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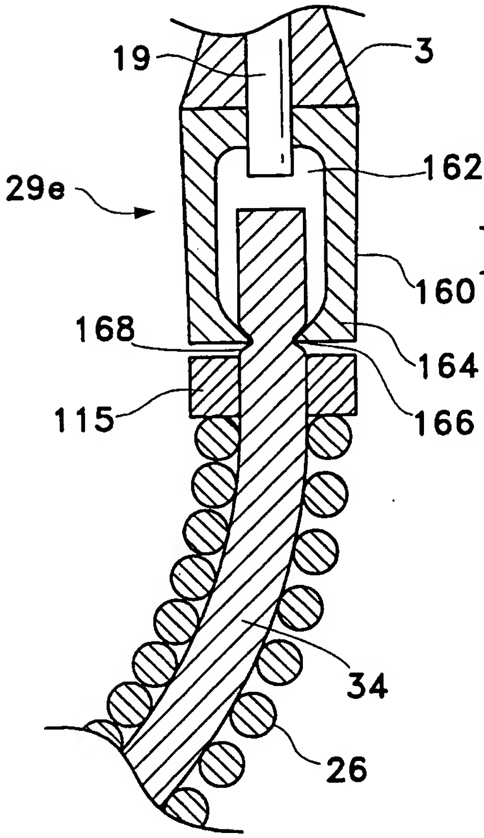


Fig. 16A

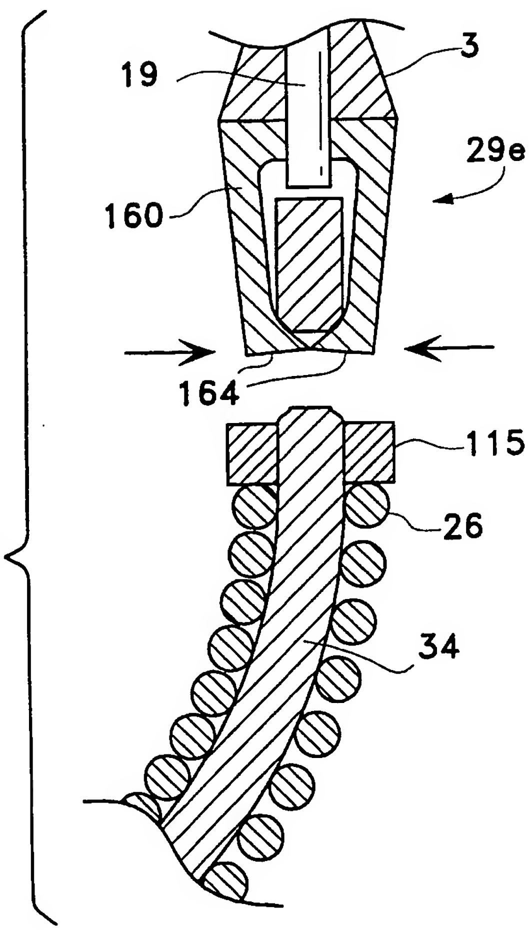
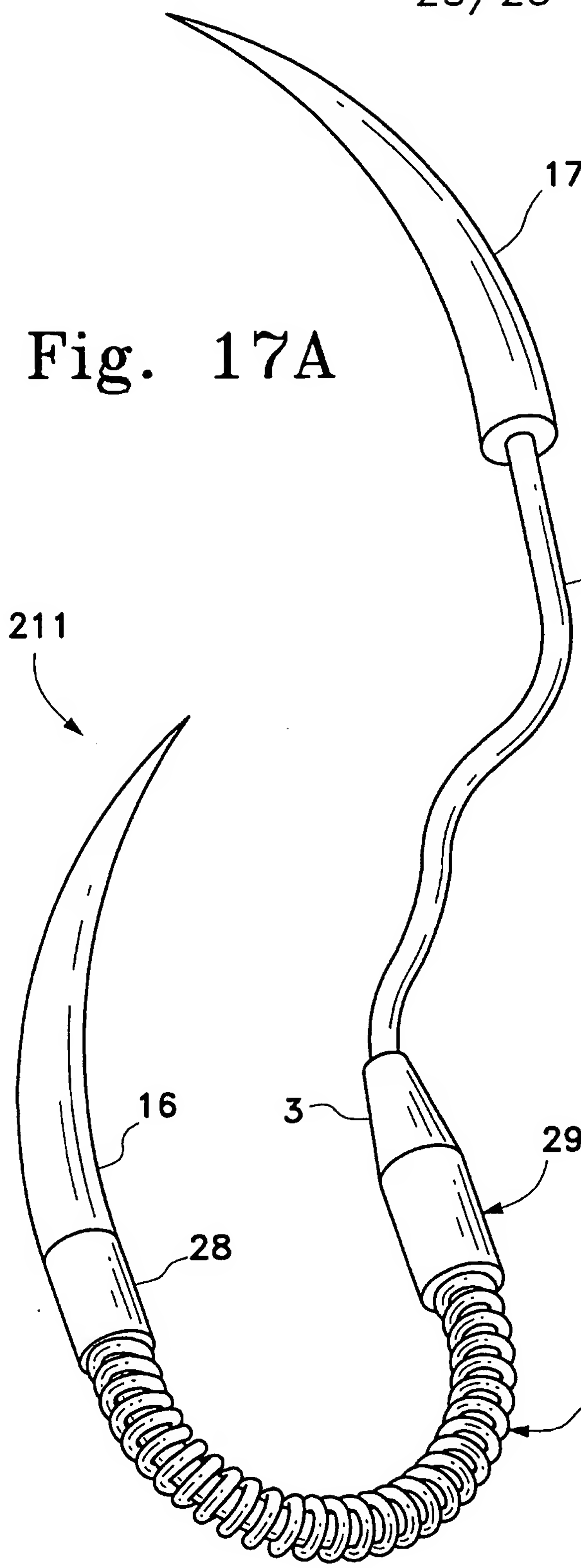


Fig. 16B

Fig. 17A



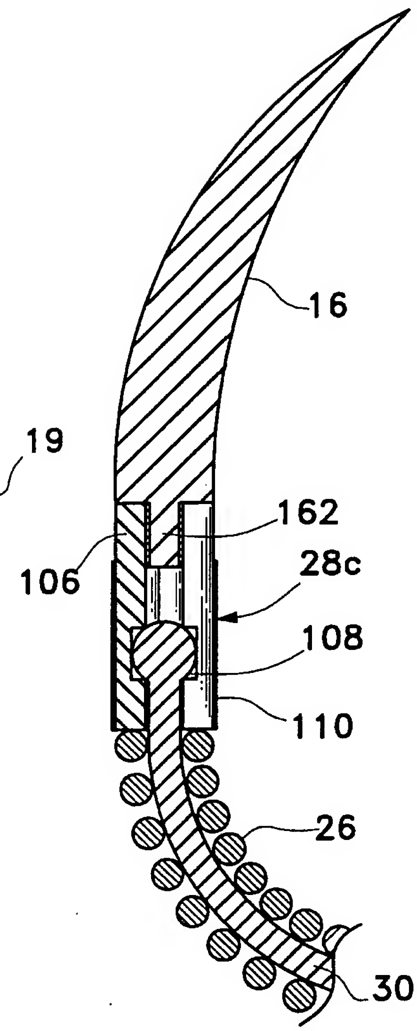
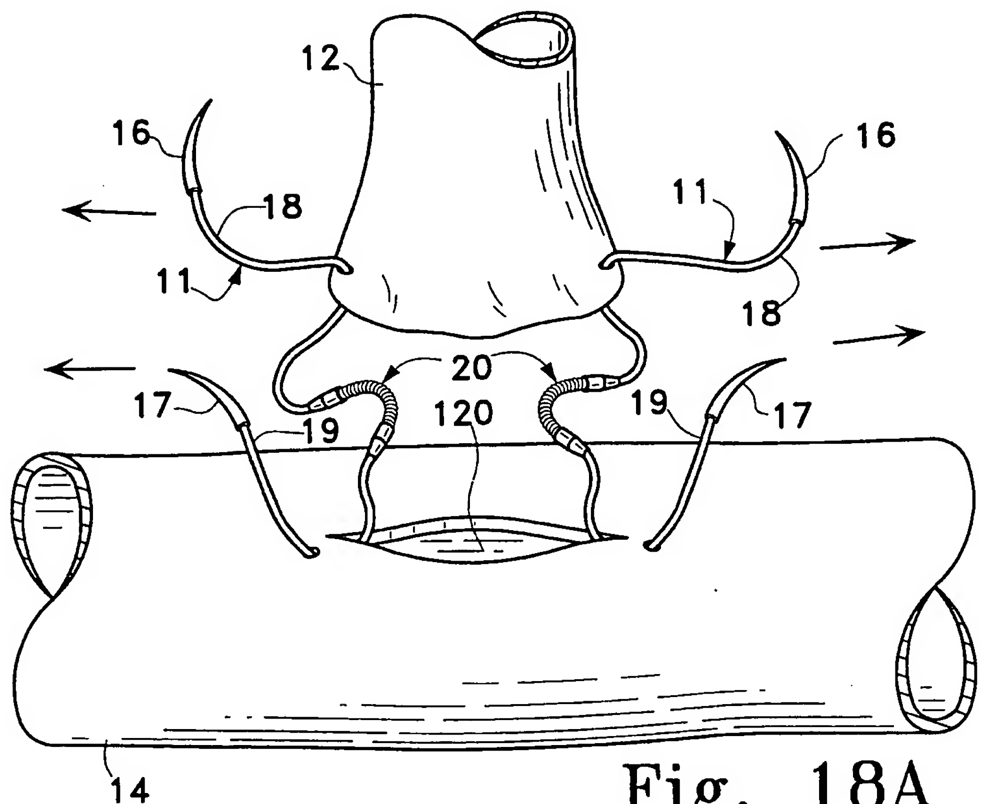


Fig. 17B



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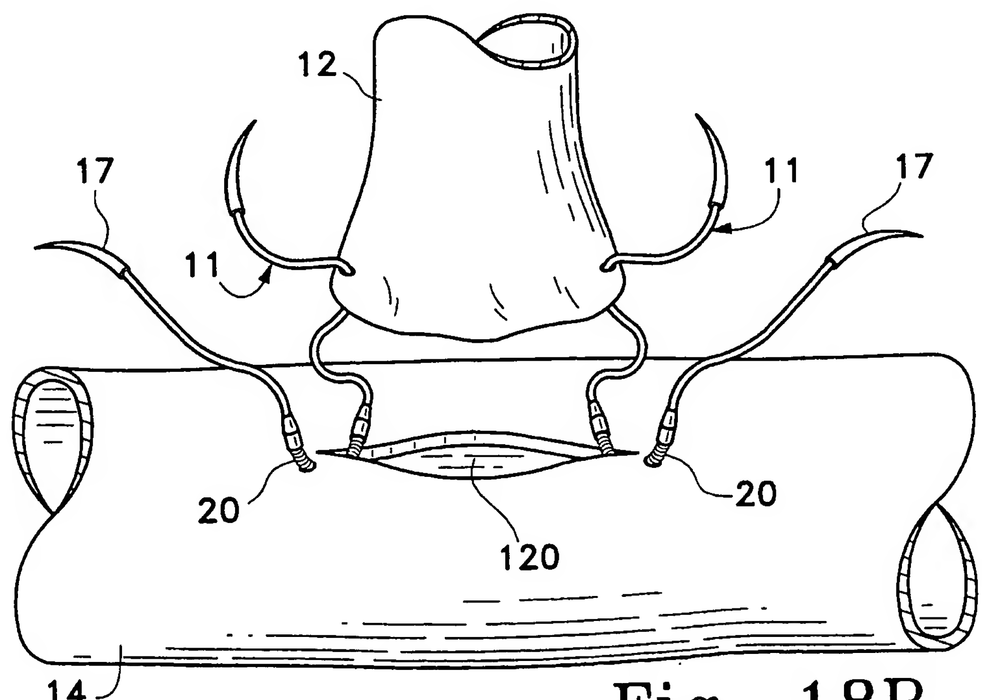

Fig. 18B

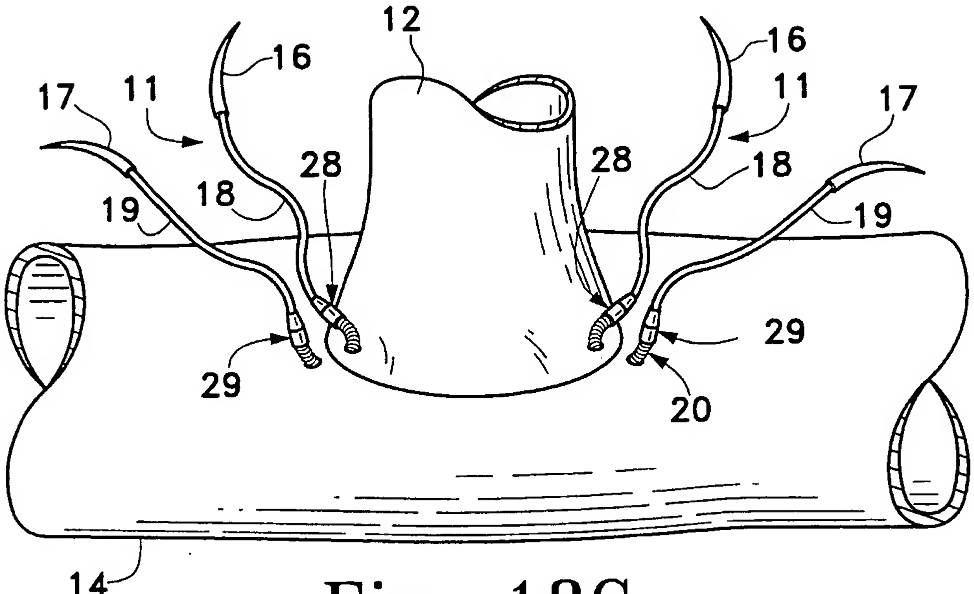

Fig. 18C

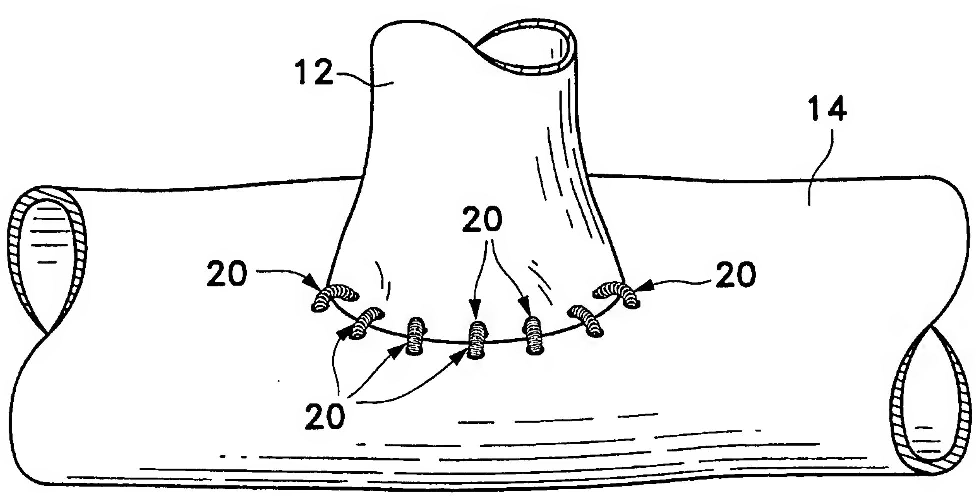

Fig. 18D

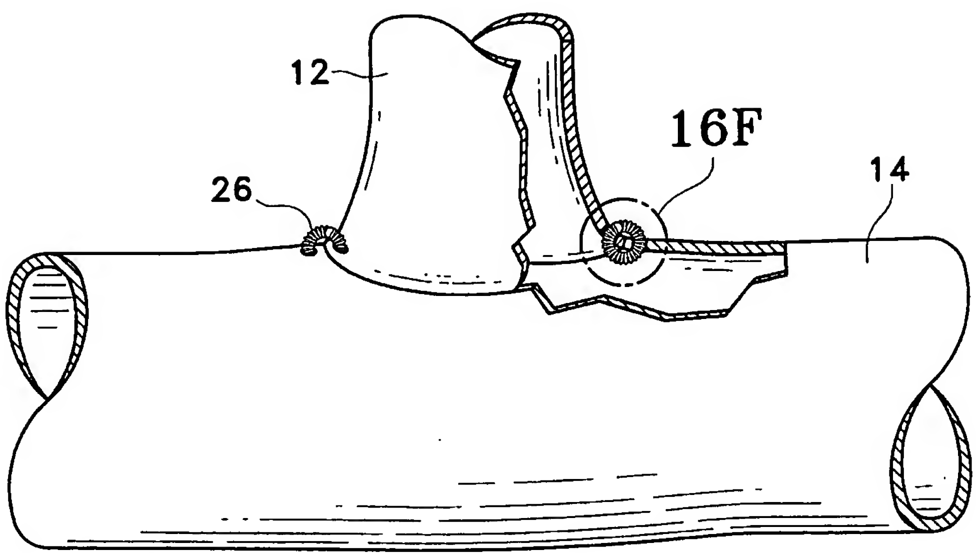

Fig. 18E

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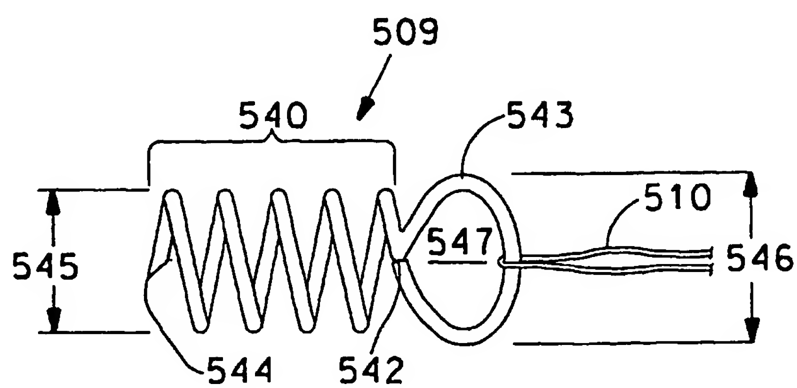
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SURGICAL METHOD FOR TREATING URINARY INCONTINENCE, AND APPARATUS FOR USE IN SAME



(57) Abstract: A surgical method for treating urinary incontinence is performed by securing a suture (510) within a patient's body, retrieving a portion of the suture (510) into the patient's vagina, and supporting the patient's urethra using the suture (510). A surgical method for elevating a patient's urethra in order to treat urinary incontinence is also performed by securing an anchor (509) in a patient. A helical anchor (509) and an anchor-insertion tool (550) are provided.

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SURGICAL METHOD FOR TREATING URINARY INCONTINENCE, AND APPARATUS FOR USE IN SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed towards a bone anchor-insertion tool, a suture retriever, a surgical template and a surgical method employing the same, all of which are particularly suited for a laparoscopic urethropexy procedure for the correction of female stress urinary incontinence. More particularly, the present invention provides apparatus and methods for performing the urethropexy through laparoscopic techniques, thereby greatly reducing the duration, discomfort, and recovery period of such surgeries.

2. Description of Related Art

Female stress urinary incontinence (SUI), defined as the unintentional loss of urine, can be a socially unacceptable problem for many women. Most often, the incontinence occurs during coughing, sneezing, or physical activity in women afflicted with this problem. While effective surgical treatment for this condition has existed for nearly 50 years, the procedures typically involve major abdominal surgery with accompanying post-operative limitations lasting six to eight weeks. Because of the nature of these surgical procedures, many women simply resort to diaper-like incontinence pads, or simply avoid any activities which result in the unintentional loss of urine.

In the normal resting state, the external pressure exerted on the collapsible urethra by the surrounding musculature is greater than the pressure exerted on the bladder, and therefore continence is maintained. During moments of coughing, sneezing, or physical activities, greater pressure will be exerted on the dome of a filled bladder. In women not afflicted with stress incontinence, a corresponding increase in the external pressure on the urethra acts to prevent the unwanted loss of urine from the bladder. Sufferers of SUI, however, aren't so fortunate.

Stress incontinence is generally caused by two etiologies: a spastic detrusor muscle; or a loss of support of the periurethral tissue at the urethra-vesicular junction ("UVJ" - the region where the urethra enters the bladder). When the latter situation occurs, the UVJ will sag into the vagina, thereby reducing the pressure which can be exerted on the urethra during moments of stress. Diagnosis of any sagging of the UVJ can be easily determined by inserting the tip of a cotton swab into the urethra until it reaches the UVJ. The patient is then asked to bear down as if urinating, and loss of the UVJ support is readily identified by the upward movement of the wooden end of the cotton swab. In this test, the external urethral meatus acts as a fulcrum for the tip of the swab, and the elevation of the opposite end indicates the downward descent of the UVJ. U.S. Patent No. 4,072,144 provides an alternative device which may be utilized to readily measure the angle of the UVJ in a similar manner.

The first urethropexy procedure for eliminating SUI caused by a sagging urethra was developed in 1948 by Drs. Marshall, Marchetti, and Krantz, and generally involves the fixation of the periurethral tissue at the UVJ on either side of the urethra (MMK procedure). Fixation in the MMK procedure, also known as urethropexy or abdominal culposuspension, is accomplished by suturing the periurethral fascia at the UVJ on either side of the urethra to the periosteum of the pubic bone. The procedure essentially alters the angular relationship between the urethra and bladder by elevating the UVJ, and therefore preventing

the sagging of the UVJ when downward pressure is applied to the region by various stresses.

The MMK procedure has been perfected over the years, however the essential principles have remained the same. In 1955 Burch developed the technique of affixing the periurethral fascia bilaterally to Cooper's ligament, thereby resulting in a technically easier procedure because of the previous difficulties in passing a needle through the periosteum of the pubic bone. Although the Burch procedure has been performed laparoscopically, the five-year failure rate for the open Burch procedure is approximately 60%. A laparoscopic Burch procedure is even more problematic since it is extremely difficult and time-consuming to tie sutures laparoscopically.

Alternatively, urological procedures such as that of Stamey, Raz and Peyerra have been developed, however these are typically blind procedures which require the passing of long needles through the rectus fascia to the periurethral fascia utilizing a cystoscope. Although these urological procedures avoid the 10-centimeter midline or Pfannenstiel incision and its required three-day or longer hospital stay, the gynecological procedures of MMK, Burch and others have proven to be the most effective. In fact, the scarring of the urethra and interior bladder as well as the scarring of the periurethral tissues, aids in fixation of all of the involved tissues during the MMK and Burch procedures, thereby assisting in the prevention of incontinence.

Recently, a modified version of the MMK procedure has been developed which utilizes bone anchors secured directly to the pubic bone on either side of the symphysis for fixation of the UVJ. The apparatus for performing this modified MMK procedure are sold by Mitek Surgical Products, Inc. of Norwood, Massachusetts, and a number of U.S. patents concern these products (*see, e.g.*, US Patent No's 5,207,679, 5,217,486 and 4,899,743). In the Mitek-MMK procedure, a Pfannenstiel incision must be made in the abdomen in order to provide access to the space of Retzius. The space of Retzius is in actuality a

"potential" space in that it contains various connective tissues and fats which must be dissected in order to provide sufficient access to this region. In fact, this connective tissue, particularly the areolar adventitial tissue, generally breaks down after delivery of a child, and this breaking down of the connective tissue often contributes to the onset of SUI in many women.

Once the space of Retzius has been dissected in the Mitek-MMK procedure, small anchors are secured in the pubic bone on either side of the pubic symphysis. Each of the bone anchors has a suture attached thereto, and these sutures are threaded through the periurethral tissue on either side of the urethra. The sutures are then tied off in the abdomen so that the periurethral tissue is pulled upward, which in turn restores the angle of the urethra at the UVJ, thereby restoring the urethra to its proper location. While the Mitek-MMK procedure is highly effective, it is a lengthy and complicated procedure which can generally only be performed by highly-skilled surgeons.

The present invention offers a unique anchor-insertion tool for securing an anchor within a patient. This apparatus is particularly suited for laparoscopic urethropexy, however, its use is not so limited.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the present invention, it is believed that the same will be better understood from the following description taken in conjunction with the accompanying drawings in which:

Figure 1 is a cross-sectional view taken through the midline of a patient who has lost support of the periurethral tissue at the UVJ, and is thereby suffering from stress urinary incontinence (SUI);

Figure 2 is the same view as Fig. 1, however the structural defect has been corrected using the methods and apparatus of the present invention;

Figure 3 is a top plan view of a bone anchor used in the method of the present invention;

Figure 4 is a side plan view of the bone anchor of Fig. 3;

Figure 5 is a top plan view of a drill tamper tool of the present invention wherein a portion of the tool has been broken-away;

Figure 6 is a side plan view of the tamper tool of Fig. 5;

Figure 7 is an end plan view of the tamper tool of Fig. 5, taken along line 7-7 thereof;

Figure 8 is a top plan view of a bone anchor insertion tool of the present invention, wherein a portion of the tool has been broken-away;

Figure 9 is a side plan view of the insertion tool of Fig. 8;

Figure 10 is a side plan view of the insertion tool of Fig. 8 with the bone anchor of Fig. 3 loaded thereon;

Figure 11 is a side plan view of a suture retriever of the present invention;

Figure 12 is an end plan view of the suture retriever of Fig. 11, taken along the line 12-12 thereof;

Figure 13 is a top plan view of a suture template of the present invention;

Figure 14 is a side plan view of the template of Fig. 13;

Figure 15 is a bottom plan view of the template of Fig. 13;

Figure 16 is an end plan view of the template of Fig. 13, taken along line 16-16 thereof;

Figure 17 is a perspective view of the template of Fig. 13 in use during a surgical procedure with portions of the patient's anatomy cut-away for clarity;

Figure 18 is a perspective view of an alternative embodiment of the suture template according to the present invention;

Figure 19 is a perspective view of the insertion tool of Fig. 8 in use during a surgical procedure with portions of the patient's anatomy cut-away for clarity;

Figure 20 is a perspective view of the surgical procedure of the present invention wherein portions of the patient's anatomy cut-away for clarity, and wherein the suture retriever of Fig. 11 is being employed;

Figure 21 is a perspective view of the surgical procedure of the present invention wherein portions of the patient's anatomy cut-away for clarity, and wherein the sutures have been retrieved from the pre-peritoneal region for tying;

Figure 22 is a perspective view of the space of Retzius, and illustrates the proper placement of the anchors and sutures employed in the present invention;

Figure 23 is a side plan view of the anchor of the present invention in place in the pubic bone of a patient, wherein the pubic bone is shown in cross-section;

Figure 24 is a perspective view of the anchor of Fig. 23;

Figure 25 is a side plan view of the anchor of Fig. 23;

Figure 25a is another side plan view of the anchor of Fig. 23;

Figure 26 is a top plan view of the anchor of Fig. 23;

Figure 27 is an end plan view of the anchor of Fig. 23, viewed from the proximal end towards the distal end;

Figure 28 is an end plan view of another embodiment of an anchor according to the present invention, viewed from the proximal end towards the distal end;

Figure 29 is an end plan view of another embodiment of an anchor according to the present invention, viewed from the proximal end towards the distal end;

Figure 30 is a cross-sectional view of the anchor of the present invention taken along the line 30-30 of Fig. 26;

Figure 31 is a side plan view of an anchor-insertion tool of the present invention, wherein a portion of the tool has been cut-away for clarity;

Figure 32 is a side plan view of the anchor-insertion tool of Fig. 31 with an anchor loaded thereon, said anchor having a suture extending therefrom, wherein a portion of the tool has been cut-away or cross-sectioned for clarity;

Figure 33 is a cross-sectional view of the loaded anchor-insertion tool of Fig. 32 taken along line 33-33;

Figure 34 is a cross-sectional view of the loaded anchor-insertion tool of Fig. 32 taken along line 34-34;

Figure 35 is a cross-sectional view of the loaded anchor-insertion tool of Fig. 32 taken along line 35-35;

Figure 36 is an end plan view of the handle of the anchor-insertion tool of Fig. 31.

Figure 37 is a top plan view of yet another embodiment of the anchor-insertion tool of the present invention, wherein a portion of the shaft has been broken away;

Figure 38 is a side plan view of the anchor-insertion tool of Fig. 37;

Figure 39 is a top plan view of the tip portion of the anchor-insertion tool of Fig. 37;

Figure 40 is a side plan view of the tip portion of the anchor-insertion tool of Fig. 37;

Figure 41 is a top plan view of the anchor-insertion tool of Fig. 37, with a pair of suture threaders loaded therein;

Figure 42 is a top perspective view of an alternative embodiment for the surgical template of the present invention;

Figure 43 is a bottom perspective view of an alternative embodiment for the surgical template of the present invention;

Figure 44 is a top plan view of another embodiment of the drill tamper tool of the present invention, wherein a portion of the shaft has been broken away;

Figure 45 is a side plan view of the drill tamper tool of Fig. 44;

Figure 46 is a side plan view of another embodiment of the suture retriever of the present invention;

Figure 47 a top plan view of the suture retriever of Fig. 46;

Figure 48 is a side plan view of the retrieving end of the suture retriever of Fig. 46;

Figure 49 is a side plan view of an anchor according to another embodiment of the present invention;

Figure 50 is a cross-sectional view of another embodiment of an anchor-insertion tool according to the present invention;

Figure 51 is an end plan view of the anchor-insertion tool of Fig. 50;

Figure 52 is a cross-sectional view of the distal end portion of the anchor-insertion tool of Fig. 50, with the anchor of Fig. 49 loaded therein;

Figure 53 is an end plan view of the anchor-insertion tool of Fig. 50, with the anchor of Fig. 49 loaded therein;

Figure 54 is a cross-sectional view of yet another embodiment of an anchor-insertion tool according to the present invention;

Figure 55 is an end plan view of the anchor-insertion tool of Fig. 54; and

Figure 56 is a cross-sectional view of the distal end portion of the anchor-insertion tool of Fig. 54, with the anchor of Fig. 49 loaded therein.

SUMMARY OF THE PREFERRED EMBODIMENTS

One embodiment of the present invention provides a surgical method for treating urinary incontinence, comprising:

(a) securing a suture within a patient's body;

(b) retrieving a portion of the suture into the patient's vagina; and

(c) supporting the patient's urethra using the suture.

A suture retriever may be vaginally inserted into the patient's body in order to retrieve a portion of the suture into the patient's vagina, and the step of supporting the patient's urethra using the suture may comprise securing the suture to the periurethral tissue adjacent the urethra. For example, the suture may be secured to the periurethral tissue by retrieving a portion of the suture through the periurethral tissue into the patient's vagina and thereafter tying the suture. The suture retriever may be configured such that it has a retrieving end which is urged through the periurethral tissue into the patient's body. In one embodiment, the retrieving end comprises a shaft with a sharp tip at one end thereof, such that the step of vaginally inserting the suture retriever into the patient's body comprises inserting the retrieving end into the patient's vagina, and thereafter urging the tip through the vaginal mucosa and periurethral fascia into the patient's body. The suture retriever may also include a handle, and at least a portion of the handle may remain outside of the patient's vagina during the retrieval step.

The suture may be secured within the patient's body by a bone anchor, such as by securing the bone anchor to the patient's pubic bone under laparoscopic vision (e.g., through the operative channel of a laparoscope). The bone anchor may include an aperture through which the suture extends such that a pair of suture tails extend away from the anchor. In this manner, the step of retrieving a portion of the suture into the patient's vagina may comprise snaring one of the tails with the retrieving end of the suture retriever, and thereafter withdrawing the retrieving end into the patient's vagina so as to retrieve the tail into the vagina. Each of the suture tails may be separately retrieved into the patient's vagina, so that the tails may be tied to one another within the vagina in order to support the patient's urethra.

In an alternative embodiment, the suture may be secured within the patient's body by a helical anchor, such as by securing the helical anchor to

Cooper's ligament. By way of example, the helical anchor may be secured to Cooper's ligament under laparoscopic vision (e.g., through the operative channel of a laparoscope). The helical anchor may include an aperture through which the suture extends such that a pair of suture tails extend away from the anchor, and the step of retrieving a portion of the suture into the patient's vagina may comprise snaring one of the tails with the retrieving end of the suture retriever, and thereafter withdrawing the retrieving end into the patient's vagina so as to retrieve the tail into the vagina.

Another embodiment of the present invention provides a surgical method for elevating a patient's urethra in order to treat urinary incontinence, comprising:

(a) inserting a laparoscope into a patient;

(b) securing an anchor within the patient under laparoscopic vision; and

(c) suspending the periurethral tissue adjacent the patient's urethra from the anchor, thereby elevating the urethra to the desired angle.

The anchor may be secured to the patient's pubic bone through the operative channel of a laparoscope, or a helical anchor may be employed wherein the helical anchor is secured to Cooper's ligament and the periurethral tissue is suspended from the helical anchor by a suture.

The present invention also provides an anchor-insertion tool for securing an anchor to a structure within a patient's body, wherein this tool comprises an elongate shaft having distal and proximal ends, an anchor-receiving tip at the distal end, and a flexible dissection pad (such as an absorbent pad) at the proximal end. The anchor-receiving tip may comprise a chamber for receiving an anchor therein, and may further include at least one slot extending radially away from the chamber. A lumen may extend at least partially through the interior of the shaft.

A loaded anchor-insertion tool is also provided, and comprises, in combination, the anchor-insertion tool described above, and a helical anchor

engaged with the anchor-receiving tip of the insertion tool. A suture may extend away from the anchor.

A helical anchor for attaching a suture to tissue is also provided by the present invention, and comprises:

(a) a helical portion comprising a plurality of helical coils, and having proximal and distal ends; and

(b) a loop portion at the proximal end of the helical portion.

The diameter of the loop portion may be greater than the diameter of the helical portion, and the loop portion may be positioned substantially normal to the helical portion.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings in detail, wherein like numerals indicate identical elements throughout the views, Fig. 1 is a cross-sectional view taken along the midline of a patient suffering from stress urinary incontinence (SUI). For reference, Fig. 1 depicts bladder 1, urethra 2, urethra-vesicular junction (UVJ) 3, periurethral tissue 4, vagina 5, uterus 6, pubic symphysis 7, and space of Retzius 8. In this patient, urethra 2 and the associated periurethral tissue 4 have sagged into vagina 5. During periods of stress such as coughing or sneezing, pressure will be exerted on bladder 1. Due to the collapse of urethra 2, the surrounding musculature will be unable to provide sufficient counteractive pressure on urethra 2 to prevent loss of urine during these periods of stress. As known from the methods of the prior art, particularly the MMK procedure, fixation of periurethral tissue 4 at UVJ 3 on either side of urethra 2 will act to support the urethra and prevent the sagging of urethra 2 into vagina 5. This in turn will enable the surrounding musculature to provide sufficient pressure on urethra 2 to prevent loss of urine during moments of stress.

Figure 2 depicts the resulting support of urethra 2 at UVJ 3 by means of the surgical procedure of the present invention. It should first be noted that

pubic bone 12 is shown in Figure 2, and is that portion of the pubic bone lying immediately to the right of the pubic symphysis. As will be more fully understood later, the anchors of the present invention are secured in the pubic bone on either side of the pubic symphysis. A bore 13 has been produced in pubic bone 12, and anchor 9 has been secured within bore 13. It should be noted that bore 13 and anchor 9 have been enlarged for purposes of clarity. A suture 10 is secured to anchor 9, and the two tails of suture 10 extend downwardly through the space of Retzius 8 into vagina 5. The tails of suture 10 extend into the vagina immediately to the right of urethra 2 through periurethral tissue 4 at UVJ 3. In the vagina, the two tails of suture 10 are tied to one another such that suture 10 provides an upward force on periurethral tissue 4 on the right side of urethra 2 adjacent UVJ 3. An identical anchor and suture combination is secured to the pubic bone on the left side of the pubic symphysis, and the suture enters the vagina in a similar fashion as before in order to provide an upper force on periurethral tissue 4 on the left side of urethra 2. In this fashion, the sutures on either side of the urethra act to restore the angle of the urethra at the UVJ.

As will be described in further detail below, the securing of the anchors to pubic bone 12 can be accomplished laparoscopically. Suture 10 may then be pulled into vagina 5 through periurethral tissue 4 immediately adjacent to urethra 2. The two tails of suture 10 may then be tied to one another within vagina 5 by hand. It has been found that the portion of suture 10 positioned within vagina 5 will be epithelialized within a few days after the procedure. In this fashion, suture 10 will not cause any discomfort or irritation to the patient since suture 10 will quickly be covered by the epithelium of vagina 5.

SURGICAL TECHNIQUE

A. Preparatory Procedures

Identification of patients suitable for the techniques of the present invention may be made by any of the known techniques for identifying patients amenable to SUI correction by MMK or similar procedures. For example, as

discussed previously a cotton swab may be inserted into the urethra until the end of the swab reaches the UVJ. The patient is then asked to bear down and the movement of the portion of the swab outside of the urethra is monitored. The external urethral meatus will act as a fulcrum for the cotton swab, and a loss of urethral support at the UVJ can be readily identified by the upward movement of the external end of the cotton swab. This indicates a downward descent of the urethra at the UVJ, which in turn provides an indication of the structural cause of the patient's SUI. Other means known in the art, however may be employed to confirm the diagnosis and/or to rule out other possible causes.

The preoperative preparation of the patient follows standard procedures for laparoscopic and gynecological surgeries, however no enema is needed. The patient is placed in the dorsal lithotomy position, and standard parenteral antibiotics are applied. Preferably, the patient is also placed under general anesthesia in order to minimize discomfort.

A Foley catheter (16 French with 10cc balloon) is then inserted into the urethra. The balloon of the Foley catheter is inflated, and the catheter is gently pulled outwardly to ensure proper placement of the balloon at the juncture of the bladder and the urethra. Proper placement of Foley catheter 14 is shown in Fig. 17 wherein a portion of vagina 5 has been cut-away for purposes of clarity. Bladder 1 is thereafter drained in the usual fashion using the catheter so that the bladder will become deflated. As will be understood below, maintaining the bladder in a deflated state greatly simplifies the procedure of the present invention. In addition, when the template of the present invention is employed, it is preferable that Foley catheter 14 be positioned in the manner shown in Fig. 17 for reasons which will be described further herein.

It is also desirable to measure the length of the patient's urethra in order to ensure proper placement of the supporting sutures, particularly when the template of the present invention is employed. If the sutures are placed too close to the bladder, there is a considerable risk that the suture retrieving tool will

puncture the bladder. Likewise, if the sutures are placed too far from the UVJ, then proper support of the urethra will not be accomplished. The length of urethra 2 may be readily measured by means of any suitable apparatus which may be inserted into the urethra, as long as the surgeon can be certain that one end of the device is positioned at the juncture of the bladder and the urethra (i.e., the UVJ). The simplest means of obtaining this measurement is to provide graduations along at least a portion of the length of Foley catheter 14, as shown in Fig. 17. In this fashion, when the balloon of the Foley is properly inflated within the bladder and the catheter pulled outwardly to ensure proper seating of the balloon at the juncture of the bladder and the urethra, the length of the urethra can be determined using the graduations which will be readily visible immediately adjacent the end of urethra 2. While the average urethra is 3 cm in length, this can often vary between about 2.7 and about 3.3 cm. As will be more fully understood below, the suture template employed in the method of the present invention can thus be manufactured in different sizes to accommodate the differing urethra lengths. A minimum of two sizes for the template may be provided, and more preferably at least three different sizes. Alternatively, the graduations may be employed to facilitate proper placement of a single-sized template.

After the placement of Foley catheter 14 and drainage of bladder 1, an infra umbilical incision is made in the patient in order to provide access to the pre-peritoneal region (the area between the abdominal wall and the peritoneum), and more particularly space of Retzius 8. Surgical dissection of space of Retzius 8 is necessary in order to provide visual access to the pubic bone for placement of the bone anchors. Thus, dissection is performed below the fascia, thereby eliminating the adventitial or supportive connective tissue in space of Retzius 8. Although dissection of the connective tissue in space of Retzius 8 can be accomplished in the typical fashion through a laparoscope, Applicant has found that a balloon dissection procedure is simpler and more effective.

Balloon dissection can be accomplished using the SPACEMAKER surgical balloon dissector manufactured by General Surgical Innovations of Portola Valley, California, and described in U.S. Patent No. 5,496,345, which is herein incorporated by reference. Other equivalent devices can also be employed for this purpose. The SPACEMAKER has a guide rod to which a small balloon is attached. The guide rod is inserted into the infraumbilical incision until the tip of the rod reaches the pubic symphysis in the space of Retzius (i.e., between the symphysis and the bladder). The balloon is then inflated in space of Retzius 8 by filling the balloon with approximately 300cc of saline solution or other suitable fluid, thereby further deflating bladder 1 and separating the surrounding connective tissue in order to provide sufficient room in space of Retzius 8 for the fixation procedure of the present invention. The balloon is then aspirated and removed from the pre-peritoneal region.

Although the SPACEMAKER device has an integral trocar sleeve which may normally be left in the infraumbilical incision for placement of the laparoscope, the only size currently available is too small for the procedure of the present invention. Obviously a properly sized integral trocar sleeve could remain in the patient after removal of the deflated balloon. Alternatively, and as presently preferred, the SPACEMAKER device is removed in its entirety, and a larger 12mm trocar is inserted into the infraumbilical incision. A 12mm WOLF operating/laser laparoscope (preferably with a WOLF 50/50 beamsplitter camera) is inserted into the trocar sleeve. The pre-peritoneal region is then insufflated, preferably with CO_2 at a pressure between about 10 and about 30 mm Hg, thereby further expanding the space of Retzius and providing excellent laparoscopic vision in this region.

Although the balloon dissection procedure is highly effective, further dissection of the space of Retzius is typically necessary in order to provide the necessary access to the pubic bone and the periurethral tissue. Although this may be accomplished by means of a CO_2 laser or a electrocautery device through the laparoscope already inserted, it is presently preferred that an

additional 5mm trocar be inserted in the midline suprapubically. An irrigation/suction/bovie device (such as that manufactured by US Surgical) is then inserted into the space of Retzius through the smaller trocar sleeve. It should be noted that the trocar sleeve, like the operative channel of the laparoscope, is cannula through which surgical instruments may be inserted. The irrigation/suction/bovie device will not only assist in further dissection of the space of Retzius, but will also provide the necessary irrigation and suction while the other instruments necessary for performing the present procedure are employed through the infraumbilical trocar sleeve. The result of further dissection is that vision far superior to the standard MMK or Burch procedures employing a full abdominal incision will be provided, since it is difficult in these procedures for the surgeon to see the underside of the pubic bone where the anchors must be placed without the surgeon placing his or her head on the stomach of the patient. In this fashion, unobstructed laparoscopic access to the pubic bone and the periurethral tissue necessary for performing the procedure of the present invention is provided.

B. Creation of Bore in Pubic Bone

It should initially be noted that the procedure of the present invention may be employed with any of a variety of bone anchors, provided that the anchor can be readily secured to the pubic bone and a suture can be attached thereto. It is presently preferred, however, that the MITEK bone anchors disclosed in U.S. Patent No. 5,207,679 (herein incorporated by reference) be employed for this purpose. As discussed more fully herein, these anchors are secured in place by pressing them into properly-sized bores created in the pubic bone. Additional types of anchors include those disclosed in U.S. Patent No's 5,522,845, 5,520,696, 5,192,303 and 5,527,342 (all of which are herein incorporated by reference). The Acufex Microsurgical, Inc., subsidiary of the American Cyanamid Co., of Stamford, Connecticut also manufactures yet another type of anchor which may be employed in the surgical procedure of the present invention. Known as TAG anchors, the Acufex anchors are disclosed in U.S. Patent No's 5,258,016, 5,100,417 and 5,224,946, which are also incorporated

herein by reference. Yet another suitable bone anchor is that sold by Li Medical of Boston, MA.

All of the above anchors are secured to bone by insertion into a bore previously created in the bone. Thus, the MITEK-MMK and related procedures require the use of either a mechanical drill or hand-operated awl in order to provide the bore for insertion of a bone anchor (such as those manufactured by Mitek Surgical Products, Inc.) into the pubic bone. While these devices may be readily employed with large abdominal incisions, they cannot be used through a laparoscope for a number of reasons. Most importantly, these tools must be sufficiently sharp to enable the surgeon to penetrate the hard outer layers of the pubic bone (periosteum and cortical bone). Since the field of vision through a laparoscope may be limited at times, however, it is very risky to employ such sharp implements as there is a tremendous risk of puncturing the bladder or other soft tissue in the operative area. In addition, as best shown in Fig. 12, pubic bone 12 falls away from the laparoscope at an angle of approximately 45°. The angularity of pubic bone 12 therefore provides vision and operative difficulties which are overcome by the apparatus and methods of the present invention. Simply drilling into pubic bone 12 using prior art apparatus through the laparoscope is not advisable because the drill or awl tip will tend to slide downwardly during the drilling operation because of the manner in which pubic bone 12 angles downwardly away from the laparoscope. While the drill tip may eventually penetrate the hard outer periosteum of the bone, the drill may enter at an improper location or angle due to downward slippage of the drill tip. Ideally one would like to produce a bore in pubic bone 12 which is at an angle of approximately 45-degrees to the surface of the bone into which the bore is produced. This angle may, however, be between about 20 and about 60-degrees, to thereby provide sufficient support for the bone anchor to be placed in the bore thus produced.

Applicant has developed a novel method and apparatus for creating the required bores in the pubic bone through a laparoscope. The method and

apparatus avoid the use of any sharp tips, while still enabling the surgeon to properly place the bores in the pubic bone without a risk of misalignment during the bore creation process. In order to produce the bore without a need for a sharp instrument, a laser is first employed to produce a cone-shaped crater in the pubic bone at the desired bore location. The crater is produced in the periosteum and cortical bone, thereby providing access to the soft cancellous, or tribecular, bone. In this fashion, a drill tamper tool (to be described further herein) may then be employed to create the properly-sized bore.

In order to create the starter "crater" in the pubic bone, a CO_2 laser (such as a SHARPLAN 20 watt) is inserted through the laparoscopic channel, and is employed to create a cone-shaped crater slightly larger than the diameter of the laser beam in the pubic bone on either side of the pubic symphysis. The diameter of the laser beam is preferably about 2mm, and therefore the cone-shaped crater created in the pubic bone is slightly larger than 2mm in diameter. The crater should be sufficiently deep to reach the cancellous bone. A crater is established on either side of the pubic symphysis directly above and approximately 1cm lateral to the periurethral fascia at the UVJ. Fig. 21 depicts the space of Retzius after creation of bores 9 and 17 in pubic bone 12 on either side of pubic symphysis 7. The desired placement location can be readily determined through means of the optics of the laparoscope, as proper dissection of space of Retzius 8 will provide sufficient vision for proper identification of the appropriate structures in the patient. If needed, the surgeon may use one or more fingers to press upwardly on the periurethral tissue on either side of the urethra within the vagina in order to properly position the two starter craters in the pubic bone.

Once access to the cancellous bone has been provided by the cone-shaped craters created on either side of the pubic symphysis using the laser, the bore for insertion of the anchor may be readily created using the drill tamper tool of the present invention. Since the cancellous bone is significantly softer than the periosteum or cortical bone, it is not necessary that a sharp awl or drill bit be

used to create the bore. Rather, a bluntly pointed drill tamper tool may be used, wherein the end of the tamper tool is not sufficiently sharp to puncture the bladder or other soft tissue under normal use. This provides a significant advantage in that damage to the bladder or other soft tissue structures in the patient may be readily avoided, and drill guides and the like which must be used with the MITEK instruments and similar apparatus can be avoided. As will be understood, the MITEK drill guides cannot possibly be employed laparoscopically. The laser employed to create the cone-shaped craters can be readily aligned in the proper location, without risk of slippage or other inadvertent movement during the procedure. The laser-created craters can then be readily employed to insure that the bores for anchor placement are created in the exact, desired location.

One embodiment of the drill tamper tool of the present invention is shown in Fig.'s 5-7, and comprises an elongate rigid member 20 having a distal end which comprises a conical boring tip 21. End 22 of conical boring tip 21 preferably has a cross section similar in size and shape to the crater created in the pubic bone by the laser. In this fashion, alignment of conical boring tip 21 within the crater will be relatively easy. It is also preferred that end 22 of conical boring tip 21 be blunt so that it will not penetrate soft tissue such as the bladder during normal use (i.e., not sufficiently sharp to penetrate soft tissue or organs during normal use). Certainly, however, conical boring tip 21 should be sufficiently thin and blade-like to permit boring tip 21 to create the bore in the soft cancellous bone by use of hand force through the laparoscope. In this regard, conical boring tip 21 is preferably shaped similar to a flat bladed screwdriver. Thus, boring tip 21 has tapered side surfaces 23 and 24 which terminate in portion 25 which is of a circular cross-section. The diameter of circular/cross-section portion 25 is identical to the diameter of the bore which will be created in the pubic bone. By rotating the drill tamper tool while simultaneously pressing boring tip 21 into the crater in the pubic bone, the desired bore will be readily created therein. The diameter of portion 25 is also approximately the same as the body of the anchor to be inserted into the bore.

In order to ensure sufficient support for the bone anchors of the present invention, it is also important that the anchor be seated deep within the pubic bone. In order to ensure proper depth of the bore, therefore, collar 26 is provided on the drill tamper tool. Collar 26 is of a larger diameter than conical boring tip 21, and therefore will act as a stop preventing further penetration of the drill tamper tool into the bone. Although collar 26 is shown as tapering in diameter between conical boring tip 21 and intermediate portion 27, it is also possible that collar 26 simply comprise a non-tapered end of intermediate portion 27. Intermediate portion 27 has a diameter significantly greater than that of conical boring tip 21, and is positioned on the opposite end of collar 26. Intermediate portion 27 not only allows the provision of collar 26, but also adds rigidity to the tamper tool. Intermediate portion 27, however, should be significantly smaller in diameter than the operative channel of the laparoscope so that sufficient vision of the operative region is provided. Preferably, the length of conical boring tip 21 is between about 1, and 3 cm, and most preferably about 1.4 cm. Intermediate portion 27 is preferably between about 2, and 6 cm, and most preferably about 5 cm.

In order to provide stability during the boring procedure, cylindrical guide portion 28 is also included on the drill tamper tool. Guide portion 28 has first end 29 and second end 30. First end 29 is attached to intermediate portion 27 at the opposite end of collar 26. Cylindrical guide portion 28 preferably has a diameter slightly less than the operative channel of the laparoscope. In this fashion, guide portion 28 provides the necessary stability within the laparoscope to ensure proper placement of the bores. Second end 30 of guide portion 28 is preferably attached to handle 31. While handle 31 is shown as having a flat end portion 32 and curved hand grip surfaces 33, handle 31 can be of a variety of forms and still be sufficient for purposes of the present invention. Handle 31 facilitates the proper manipulation of conical boring tip 21 through the laparoscope, and provides a sufficiently firm surface 32 upon which force may be applied to complete the boring operation. Guide portion 28 preferably has a length between about 50 and about 55 cm, and most preferably about 52 cm. The

overall length of the drill tamper tool therefore permits sufficient access to the pubic bone, while also providing an ergonomically-effective boring operation through the laparoscope and ensuring that the tool does not interfere with the anesthesiologist.

Figures 44-45 depict an alternative embodiment for the drill tamper tool of the present invention wherein the intermediate portion has been eliminated. Thus, the drill tamper tool of Fig. 44 comprises an elongate, rigid shaft 328, which corresponds to the guide portion in the embodiment of Fig's 5-7. At one end of shaft 328 is handle 331 which serves the same purpose as described previously. At the opposite end of shaft 328 is boring tip 321. Boring tip 321 is as described previously, and thus has blunt end 322, circular cross-section portion 325, and tapered side surface 323 (the opposite tapered side surface is not visible). Collar 326 is positioned between boring tip 321 and shaft 328, and once again acts as a stop to limit penetration to the desired depth. Collar 326 is preferably tapered as shown in order to provide sufficient laparoscopic vision. Boring tip 321 has a length of between about 1 and about 3cm, preferably about 1.4 cm. Shaft 328 has a length of between about 45 and about 60 cm, preferably between about 50 and about 52 cm, thereby providing laparoscopic access to the pubic bone. Shaft 328 also preferably has a diameter which is only slightly less than the operative channel of the laparoscope in order to provide stability and prevent insufflation gas from escaping. While end 322 of tip 321 may be blunt as previously described, in the embodiment of Figs. 44-45 it has a pointed tip.

C. Insertion Of Bone Anchors In Pubic Bone

One preferred anchor for use in the present invention is shown in Figs. 3 and 4, and is identical to that disclosed in U.S. Patent No. 5,207,679. Anchor 9, which is preferably made of titanium alloy or other suitable material, has a cylindrical body 40 and a conical end 44 attached thereto. At least two flexible barbs 41 curve outwardly away from body 40. A groove 42 is provided on either

side of body 40 at the end opposite to conical end 44. In addition, cylindrical end 45 extends away from body 40 adjacent groove 42. The longitudinal axis of cylindrical end 45 is aligned with the longitudinal axis of body 40. The diameter of cylindrical end 45 is preferably equivalent to the diameter of body 40 within grooves 42 positioned on opposite sides of body 40. As will be understood below, this structure facilitates the attachment of anchor 9 to an insertion tool.

As best shown in Fig. 4, body 40 and cylindrical end 45 have an aperture 43 provided therethrough. Aperture 43 is sized so as to accommodate a suture appropriate for the fixation procedure of the present invention. It is preferred that a size 0 GORE-TEX suture be employed, and thus anchor 9 and its accompanying aperture 43 should be sized accordingly. The use of a GORE-TEX suture is preferred for reasons of strength and non-elasticity. Certainly other types of sutures could be employed if necessary. A portion of suture 10 is shown in Fig. 3 having been inserted through aperture 43.

The insertion of anchor 9 is relatively straightforward, and merely requires that the anchor be pressed completely into the bore which has previously been created in the pubic bone. Preferably, anchor 9 is inserted into the bore in the pubic bone until conical end 44 reaches the distal end of the bore. The bore should be at least as long as the length of anchor 9, however, it is preferably considerably longer to ensure sufficient support for the anchor. As anchor 9 is pressed into the bore, flexible barbs 41 will be compressed against body 40 as they are inserted past the hard periosteum and cortical bone surrounding the bore. Once within the bore, however, flexible barbs 41 will tend to spring back into the soft cancellous bone, thereby securing the anchor in place. A slight tug on the tails of the suture 10 will also cause barbs 41 to further deploy.

In order to insert anchor 9 into the bore previously created in the pubic bone, the anchor insertion tool shown in Fig's. 8-10 may be employed. Thus, after the drill tamper tool has been employed to create the necessary bores, the

anchor insertion tool of the present invention having an anchor and threaded suture loaded there, is inserted into the laparoscope for proper seating of anchor 9.

The anchor insertion tool of the present invention comprises a rigid elongate member 50 having a handle 51 at one end, and an anchor-receiving tip 52 at the opposite end of elongate member 50. As was the case with the drill tamper tool, handle 51 can be of any variety, and that shown is only one embodiment for this handle. Anchor-receiving tip 52 is similar in construction to that shown in Figs. 4-6 of U.S. Patent No. 5,207,679. Anchor-receiving tip 52 is constructed so as to matingly receive anchor 9 in order to facilitate insertion of anchor 9 into the bore. As will be apparent, the longitudinal axis of anchor-receiving tip 52 should be aligned with the longitudinal axis of elongate member 50. Anchor-receiving tip 52 is cylindrical in nature, having a diameter approximately equivalent to body 40 of anchor 9. In this manner, at least a portion of anchor-receiving tip 52 may pass through the bore in the pubic bone during the anchor insertion process to properly seat the anchor completely within the bore.

Anchor-receiving tip 52 has a pair of guide tabs 53 extending from the end of anchor-receiving tip 52 on either side thereof. Guide tabs 53 are sized and shaped so as to be matingly received within grooves 42 positioned on either side of anchor 9. Anchor-receiving tip 52 also has a cylindrical slot 54 aligned with the longitudinal axis of tip 52. Cylindrical slot 54 should correspond in size and shape to cylindrical end 45 of anchor 9 in order to matingly receive the same. It is also preferable that the distance between guide tabs 53 be slightly smaller than the distance between the corresponding grooves 42 on anchor 9. In this fashion, guide tabs 53 as well as cylindrical slot 54 will apply compressive force against anchor 9 thereby more securely holding anchor 9 in place when loaded within anchor-receiving tip 52.

Since suture 10 will extend outwardly on either side of anchor 9, it is preferable to provide a means for ensuring that suture 10 is not abraded by the bone surrounding the bore during the insertion process. Thus, a pair of tapered grooves 55 are provided on either side of the anchor insertion tool, and extend from the end of anchor-receiving tip 52 along at least a portion of the length of elongate member 50. As best shown in Fig. 10 wherein anchor 9 has been loaded upon the insertion tool, grooves 55 ensure that the sutures will be protected by anchor-receiving tip 52 and a portion of elongate member 50 during the insertion process. Since any nicks in the suture may compromise the strength and permanency of the fixation, it is important to ensure that the suture is not damaged in any fashion.

Anchor-receiving tip 52 should also be of the proper length to ensure deep placement of anchor 9 completely within the bore. Thus, the length of the combination of anchor-receiving tip 52 and bone anchor 9 when loaded in the manner shown in Fig. 10 should be equivalent to the size of the bore created in the pubic bone. Since the diameter of elongate member 50 is significantly greater than that of anchor-receiving tip 52, distal end 56 of elongate member 50 will firmly abut the pubic bone once the anchor has been completely inserted into the bore. In this manner, the surgeon can be certain that the anchor has been seated to its complete and proper depth.

As was the case with the drill tamper tool of the present invention, elongate member 50 further comprises an intermediate section 57 and a guide portion 58. Intermediate portion 57 should have a diameter sufficiently less than that of the laparoscope in order to provide adequate vision for the surgeon, and intermediate portion 57 also has distal end 56 described above. Preferably, intermediate portion 57 has a length between about 2 and about 6 cm, most preferably about 5 cm. It should be kept in mind that, as shown in Fig. 10, suture 10 will extend along the length of intermediate portion 57 on either side thereof. This consideration must be kept in mind when sizing the diameter of

intermediate portion 57 to ensure not only that it can be easily inserted through the laparoscope, but also to ensure adequate vision.

Guide portion 58 will necessarily be slightly smaller than the diameter of the guide portion for the drill tamper tool previously described, since, as shown in Fig. 10, suture 10 will extend along either side of guide portion 58. With this in mind, the total of the diameter of guide portion 58 and twice the diameter of suture 10 should be only slightly less than the inside diameter of the operative channel of the laparoscope. In this fashion, guide portion 28 provides a rigid support for the surgeon during the anchor insertion process. Preferably, guide portion 58 has a length between about 50 and 55 cm., most preferably about 52 cm. This provides an overall inserter length comparable to that of the drill tamper tool, thereby providing the same advantages with regard to the tamper tool length.

In order to effectively employ the procedure of the present invention laparoscopically, it is necessary that the two tails of suture 10 be controlled as much as possible. If the sutures are permitted to hang away from anchor 9 or the anchor insertion tool, the tails will generally become balled within the space of Retzius, thereby making the suture tying procedure difficult, if not impossible. Although the sutures may be held against the anchor insertion tool by hand, Applicant has developed a more effective manner of accomplishing this. Thus, first and second shouldered depressions 59 and 60 are preferably provided about the circumference of guide portion 58. A small rubber band 61 (as shown in Fig. 10), or other suitable elastic band, may be held within each of the two shouldered depressions, with the two tails of suture 10 held beneath rubber band 61 on either side of guide portion 58 as shown. First shouldered depression 59 is preferably positioned approximately 10 cm from the ends of guide tabs 53. Second shouldered depression 60 is preferably positioned about 40 cm from guide tabs 53. Both shouldered depressions act, in conjunction with an elastic band contained therein, to hold suture 10 in place on the sides of the anchor insertion tool.

In addition to holding the suture in place on the anchor insertion tool, the shouldered depression/elastic band combination further improves the laparoscopic procedure of the invention by not only assisting in seating the anchor, but also in the suture retrieval process. As shown in Fig. 20, the anchor insertion tool of the present invention, with a pre-loaded anchor and suture assembly attached thereto, is inserted through the laparoscope for placement of the anchor as previously described. Once the anchor has been seated within the bore, the anchor insertion tool is then pulled outwardly utilizing handle 51 contained thereon. The combination of shouldered depressions 59 and 60 and rubber band 61 act to provide tension in suture 10 which in turn pulls outwardly on anchor 9 which is now contained in the bore. This outward force on anchor 9 will cause flexible barbs 41 to extend outwardly into the cancellous bone surrounding the bore, thereby further securing anchor 9 in position. In other words, this outward force on suture 10 by the drag created by the shoulder depression/elastic band combination will act to deploy the previously compressed barbs 41 on anchor 9, thereby rigidly securing anchor 9 within the bore.

In order to facilitate the surgical procedure of the present invention, the drill tamper tool and the anchor-insertion tool described above may be provided in the form of a reusable surgical kit.

D. Fixation of Periurethral Tissue At the UVJ Via Suturing

Once the anchor and suture assembly have been secured within the bore created in the pubic bone, it is next necessary to utilize the two tails of the suture to elevate the periurethral tissue on the corresponding side of the urethra at the UVJ. Applicant has found that the most effective means for accomplishing this is to pull each tail of the suture through the periurethral tissue into the vagina. In this fashion, the two tails may then be easily tied to one another within the vagina to provide the necessary support, and eliminating any need for laparoscopic suture tying. Obviously, however, a means for retrieving the suture tails must be provided.

The method of suture retrieval is best shown in Fig. 20, which is a perspective view of the procedure with portions of the patient's anatomy cut-away for purposes of clarity. As shown in Fig. 20, as the anchor insertion tool of the present invention is partially withdrawn from the patient through the laparoscope, first shouldered depression 59 in combination with rubber band 61 will cause both suture tails to be tensioned between the anchor and the anchor insertion tool as shown. Were this not the case, the suture tails would merely fall into the space of Retzius similar to a ball of yarn, and thereby be difficult (if not impossible) to retrieve. While the suture tails could be tensioned between the anchor and the anchor insertion tool by pulling outwardly on the sutures, this would unnecessarily require an additional pair of hands. Thus, the shouldered depression/rubber band combination is also effective in this regard.

Once the anchor insertion tool has been partially removed in order to tension the suture tails in the manner shown in Fig. 20, a suture retrieving tool may be inserted into the vagina and then pressed upwardly on one side of the urethra into the space of Retzius in order to retrieve one of the suture tails in the manner shown. Thus, the suture retrieving tool must have a sharp point capable of passing completely through the full thickness of the periurethral fascia and vaginal mucosa adjacent the urethra. The suture retrieval tool must also have a means for grasping the suture tail and pulling the tail back through the full thickness of the periurethral and vaginal mucosa by means of the same entry hole created by the sharp point. Each tail is pulled into the vagina in this fashion at the proper location. Preferably, one tail is pulled into the vagina approximately 1 cm from the urethra at the UVJ, and the other tail is pulled into the vagina approximately 2 cm lateral from the urethra. In other words, each tail penetrates the periurethral tissue along an imaginary line extending substantially perpendicularly away from the urethra. Each tail may then be pulled out of the vagina for purposes of tying.

The suture tails are tied to one another using a series of standard surgeon's knots, and each knot is slid by hand to the point in the vagina at which

the suture tails were previously retrieved. The tails are tied to one another in a sufficiently tight fashion so that suture 10 creates an upward force on the periurethral tissue adjacent the urethra in order to elevate the urethra at the UVJ and restore the urethra to its proper angle. The position of the urethra can be readily observed by the surgeon as this procedure is performed, thereby ensuring that the urethra is restored to the desired angle. The entire procedure (anchor insertion, suture retrieval, etc.) is then repeated for the anchor placed on the opposite side of the pubic symphysis, and the suture tails of that anchor are pulled into the vagina through the periurethral tissue on the opposite side of the urethra as the first suture tails. Tying is then performed in the same fashion, thereby elevating the other side of the urethra to thereby completely restore the urethral angle at the UVJ.

The result of this process is best shown in Fig. 2, wherein it is shown that suture 10, and the corresponding suture on the opposite side of the urethra have restored the urethra to its proper angle. It should be noted that at no time do the sutures pull upward directly beneath the urethra, since doing so would create the risk that the suture would cause urethral blockage. After tying, the remaining tails of suture 10 are cut at the knot. After the suture tails have been cut adjacent to the knot, it is preferred that the knot be moved into the abdominal cavity. This can be accomplished merely by pulling lightly on one portion of the suture within the vagina, which thereby causes the suture to be pulled through one of the holes previously traded in the vaginal mucosa and periurethral fascia towards anchor 9. In other words, the suture acts much like a rope on a pulley system, such that when one portion of the tied suture is pulled downwardly into the vagina, the opposite side will traverse upwardly, carrying the knot with it into the abdominal cavity. In this manner, the knot will not be present within the vagina where it might cause irritation. The portion of suture 10 remaining in the vagina will epithelize within three to four days, and the patient will no longer sense that the sutures are in place. The result is a permanent fixation of the periurethral tissue on both sides of the urethra, thereby restoring the urethra to its correct angle and eliminating the SUI. After completion of the tying process,

the surgical area within the patient is flushed with a dilute lidocaine solution, the laparoscope and trocars removed, a stronger lidocaine solution is applied to the incision sites, and the incisions are closed in the usual fashion. The Foley catheter may then be removed, and the patient permitted to recover in the usual fashion. Normal everyday activities may be resumed within 2-3 days.

E. Suture Retriever

In order to pull the tails of suture 10 through the entire thickness of the periurethral fascia and vaginal mucosa, various tools can be employed. For example, a U.S. Surgical Auto-Stitch tool may be effectively employed for this purpose. It is critical, however, that the tool employed being capable of readily be inserted through the periurethral tissue from the vagina into the space of Retzius, while also being capable of grasping the suture tails. It is also critical that the surfaces contacting suture 10 be perfectly smooth in order to eliminate the risk of nicks or cuts in suture 10 which would obviously compromise the effectiveness of the procedure. Applicant has developed a novel suture retriever for accomplishing this purpose which provides a convenient and simple means of retrieving the suture tails.

The suture retrieval tool of the present invention is depicted in Fig. 11, and comprises metal retrieving end 65, midshaft 66, and handle 67. Midshaft 66 and handle 67 may be singularly molded from polycarbonate or a similar FDA-approved material in the typical fashion. As shown in Fig. 12, handle 67 is also preferably knurled in order to facilitate grasping and manipulation of the retriever. Metal retrieving end 65 is preferably made of stainless steel and can be securely molded into distal end 68 of midshaft 66.

Metal retrieving end 65 comprises a rigid, rod-like shaft 69, and a sharp tip 70 capable of penetrating the periurethral tissue. The diameter of distal end 68 is preferably significantly greater than that of shaft 69, and will act as a stop in order to limit the penetration of the suture retrieval tool into the space of Retzius. Thus, the length of shaft 69 and tip 70 may be selected so as to ensure

that when the suture retrieval tool is inserted into the space of Retzius through the vagina that sharp tip 70 will generally be incapable of striking any surrounding soft tissue.

Retrieving end 65 further comprises a return leg 71 which extends away from sharp tip 70 in the same direction of shaft 69. Shaft 69, return leg 71 and the underside of sharp tip 70 thus create an inverted U-shaped region capable of ensnaring suture 10 for retrieval purposes. The distance between return leg 71 and shaft 69 in the region of the inverted U-shape is preferably approximately the same diameter as suture 10. In this fashion, and as shown in Fig. 20, after sharp tip 70 has penetrated the periurethral tissue adjacent the vagina in order to enter the space of Retzius, the inverted U-shape may be pulled downwardly over a suture tail, thereby snaring the suture. Metal retrieving end 65 may then be pulled back through the periurethral tissue, and the tail of suture 10 will remain snared between return leg 71 and shaft 69 directly beneath sharp tip 70. Although the suture tail will slide within the U-shaped region, it will nevertheless be pulled into the vagina.

One critical feature of the suture retriever of Fig. 12 is that the inner surfaces of metal retrieving end 65 which contact suture 10 must be rounded and smooth in order to permit suture 10 to freely slide within the inverted U-shaped portion as the retriever is withdrawn. This prevents nicking or fraying of the suture while still permitting the suture tail to be withdrawn. Thus, the only sharp portion of metal retrieving end 65 is sharp tip 70.

While it is possible that handle 67, midshaft 66, and metal retrieving end 65 may all be positioned along the same longitudinal axis thereby forming a rigid, elongate structure, Applicant has found that the process of the present invention can be simplified if the elements of the retriever have the angular relationship indicated in Fig. 11. This is particularly true when the template of the present invention (to be described further herein) is employed. Thus, metal retrieving end 65 preferably is positioned at an angle of between about 100 degrees and

about 130 degrees, most preferably about 120 degrees, to midshaft 66 (this angle is indicated as A in Fig. 11). Likewise, handle 67 is preferably positioned at an angle of between about 100 degrees and about 130 degrees, most preferably about 120 degrees, to midshaft 66 (this angle is indicated as B in Fig. 11). Thus, the longitudinal axis of shaft 69 of metal retrieving end 65 will be parallel to the longitudinal axis of handle 67. In this fashion, when the retriever of the present invention is employed midshaft 66 will generally be positioned parallel to the longitudinal axis of the vagina. Metal retrieving end 65 will then extend upwardly through the periurethral tissue into the space of Retzius as desired. As best shown in Fig. 20, handle 67 will thereby extend downwardly outside of the vagina, and thus sharp tip 70 may be readily forced through the periurethral tissue as desired merely by pushing upwardly on handle 67.

As shown in Fig. 11, the transitions between handle 67 and midshaft 66 as well as between midshaft 66, and retrieving end 65 should be gently curved in order to ease placement. It should be noted that angles A and B can vary significantly, however it is preferred that they be as close to one another as possible so that the parallel relationship of handle 67 and retrieving end 65 is maintained. In addition, the present configuration ensures that the retrieving end 65 will enter the space of Retzius at an angle of approximately 90 degrees to the tensioned suture tails (i.e., the suture tails tensioned between the anchor and the anchor insertion tool). This parallel relationship allows for effective snaring of the suture, as well as improved vision of the retrieval through the laparoscope.

Preferably, midshaft 66 is between about 2 and about 6 cm. in length, most preferably about 4 cm. The cross-sectional area of midshaft 66 should merely be a size chosen to provide the necessary rigidity while also not blocking vision within the vagina during the procedure. Likewise, handle 67 is preferably about 4 cm long, however the length is not as critical since handle 67 remains completely outside of the body. The diameter of handle 67 should be chosen so as to provide a comfortable and secure means of grasping the suture retrieval tool. Preferably, handle 67 is about 3 cm in diameter.

An alternative, and presently preferred embodiment for the suture retrieval tool of the present invention is shown in Figs. 46-48. In this embodiment, the suture retrieval tool once again comprises metal retrieving end 265, a midshaft 266 and a handle 267. The longitudinal axis of these three elements are as shown by the dashed lines. Midshaft 266 and handle 267 may be singularly molded from polycarbonate or a similar FDA-approved material in the typical fashion. Handle 267 preferably is curved in the manner shown so as to provide a comfortable grip for the surgeon.

Metal retrieving end 265 comprises a rigid, rod-like shaft 269 and a tip of portion 270. As best shown in Fig. 47, tip portion 270 is preferably flat in nature, and, as shown in Fig. 48, has a width L which is less than the width or diameter of shaft 269. Tip 270 has a sharpened distal end 274, and a suture slot 271 located approximately of the distal end. Slot 271 also has an entrance 275 thereto, and entrance 275 is spaced inwardly from shaft 269. In other words, the center line of tip portion 270 is slightly off-set from the longitudinal axis of shaft 269. In this manner, a suture may be snared in the manner described previously by allowing the suture to enter entrance 275 until it rests within slot 271. When the tip of the suture retrieval tool is then retracted back into the vagina, the off-set between opening 275 and shaft 269 will ensure that leg 276 adjacent suture slot 275 will not snag against the patient's tissue. In other words, since shaft 269 tends to create a puncture hole in the patient's tissue which is greater than the width of tip 270, the tip will not snag on the edges of this puncture hole.

In addition, shaft 269 preferably has a diameter which is significantly greater than that of the suture employed. In this manner, shaft 269 will create a puncture hole is the soft tissue which is larger than the knot in the suture. In this manner, the knot may be moved from the vagina into the abdominal cavity of the patient through this puncture hole in the manner previously described. In order to facilitate insertion of shaft 269 into the patient, tapered walls 277 are provided. Tapered walls 277 provide a smooth transition between flat tip 270 and rounded shaft 269.

In the embodiment of Figs. 46-48, the angular arrangement of retrieving end 265, midshaft 266 and handle 267 is preferably modified somewhat from that previously described in that the angle between midshaft 266 and retrieving end 265 is greater than that previously described. Applicants have found that by opening this angle further, the surgeon will be better able to avoid striking blood vessels on the undercarriage of the pubic bone with the sharp distal end 274. Thus, while angle M between midshaft 266 and handle 267 is preferably between about 120 degrees and about 135 degrees, the angle between retrieving end 265 and midshaft 266, however, is between about 135 degrees and about 155 degrees, more preferably about 150 degrees. In order to add strength and rigidity, a small extension to 278 on midshaft 266 has a longitudinal axis corresponding to that of retrieving end 265. Extension 278 may be hollow, thereby allowing retrieving end 265 to be inserted and secured therein. The diameter of extension 278, as well as the remainder of midshaft 266, is preferably larger than that of shaft 269. This allows end 268 of extension 278 to act as a stop which prevents the midshaft from penetrating the soft tissue once the retrieving end is inserted through the soft tissue of a patient.

F. Surgical Template

While the placement of the sutures at the UVJ may be accomplished by merely feeling for the correct location within the vagina by hand, particularly in relation to the ball of the Foley catheter, Applicant has developed a novel template which greatly simplifies proper placement of the sutures. This device not only prevents bladder injury, urethral injury, or vascular accidents, the template also ensures a proper distance between the two suture tails to ensure that there is adequate periurethral tissue between the tails to provide the necessary support. Obviously if the suture tails are placed too close to one another, there is a risk that the suture will tear through the periurethral tissue and eliminate the fixation. Thus, a template is provided wherein the template has at least two apertures which may be properly positioned on either side of the urethra. The suture retriever may then be inserted through these apertures and

thereafter through the periurethral tissue in order to snare the suture tails in the manner described previously.

One embodiment for the surgical template is depicted in Figs. 13-17. The template comprises a trough 80 of arcuate cross-section, wherein trough 80 is sized so as to cradle the patient's urethra when properly positioned. First and second wing members 81 and 82 extend away from opposite sides of trough 80, preferably perpendicularly to the longitudinally axis of trough 80 in the manner shown. Most preferably wing members 81 and 82 extend perpendicularly away from opposite sides of trough 80 at the upper most edges 83 and 84 of trough 80. First and second suture guide apertures 85 and 86 are positioned in each of the wing members 81 and 82 as shown. The guide apertures are positioned so that when the urethra of the patient is properly positioned within trough 80, guide apertures 85 and 86 on each wing will indicate the proper location for the sutures. First suture guide aperture 85 is positioned so that the first tail of suture 10 will penetrate the periurethral tissue approximately 1 cm from the urethra adjacent the UVJ. Second guide aperture 86 is preferably positioned about 1 cm further away from the urethra along a line perpendicular to the longitudinal axis of trough 80. In other words, the distance between first suture guide aperture 85 and second suture guide aperture 86 is preferably about 1 cm. In this manner, the surgeon can be confident that sufficient periurethral tissue will be present between the two suture tails.

It is certainly possible that the template of the present invention may merely be held in place by hand, and in fact the downwardly sloping nature of the underside wing members 81 and 82 are suitable for placement of the surgeon's fingers thereunder. Additional alignment means are preferably provided, however at a minimum, end wall 87 is provided at the end of trough 80 furthest away from the suture guide apertures. Thus, as long as the template is properly sized for the length of the patient's urethra, the surgeon may hold the template in place with end wall 87 abutting the outermost end 89 of urethra 4 in order to ensure proper alignment. For example, if the length of the patient's

urethra is determined to be three cm, the distance between end wall 87 and first and second guide apertures 85 and 86 should be between about 2.5 and about 3.2 cm, most preferably about 2.8 cm. The guide apertures should also be between about 0.25 and about 0.5 cm from distal end 91 of the wing members (Fig. 13). As long as the template is positioned with end wall 87 abutting the outermost portion of the urethra, the surgeon will be assured that the sutures will be properly placed without risk of puncturing the bladder, or urethra.

While the surgeon may employ two fingers beneath wing members 81 and 82 to hold the template in the proper position, Applicant has found that the provision of arcuate alignment member 88 secured to end wall 87 may be effectively employed for securing the template in place without the need for the surgeon to hold the template in any manner. Alignment member 88 is preferably positioned parallel to trough 80, with the center line of alignment member 88 aligned with the center line of trough 80. Alignment member 88 may either extend away from trough 80 as shown in Fig. 13, or alternatively may extend away from end wall 87 directly along the interior of trough 80 as shown in Fig. 18.

When the embodiment of Figs. 13-16 is employed, alignment member 88 is preferably sized so that when the template is manufactured from a resilient material, alignment member 88 may be rigidly snapped about Foley catheter 14 as shown in Fig. 20. Thus, the shaft of Foley catheter will be securely held within alignment member 88, and the surgeon need only pull outwardly on the Foley catheter while sliding the template into the vagina towards the urethra until end wall 87 abuts end 89 of urethra 2. The ball of the Foley catheter will thus be positioned at the UVJ, and the template will likewise be positioned at the appropriate location assuming that a template of the proper size has been selected based upon the length of the urethra.

As an alternative to providing various sizes for the template of the present invention, a single, larger-sized template may be employed provided that

alignment member 88 is snapped about the shaft of Foley catheter 14 in the proper location. Thus, instead of abutting end wall 87 against end 89 of urethra 2, end wall 87 is instead aligned with the appropriate graduation along the shaft of Foley catheter 14 based upon the previously-measured length of the urethra. Likewise, end 90 of alignment member 88 could alternatively be aligned with the appropriate graduation along the shaft of Foley catheter 14 in order to provide the proper placement of the template based upon the length of the patient's urethra.

Fig. 18 depicts yet another alternative embodiment for the template of the present invention in which alignment member 88 extends along the interior of trough 80. In employing this embodiment, alignment member 88 is inserted into the urethra along with Foley catheter 13 until end wall 87 of the template abuts end 89 of urethra 2. As will be understood, therefor, an appropriately-sized template will ensure proper placement of the sutures.

Figs. 42-43 depict an alternative, and presently preferred, embodiment for the surgical template of the present invention. As was the case in the embodiment of Figs. 13-16, alignment member 388 extends away from trough 380. In this embodiment, alignment member 388 is tubular in nature. In addition, the longitudinal axis of alignment member 388 is positioned slightly above the longitudinal axis of trough 380. This spacing provides for more proper alignment of the template. Instead of rigidly snapping about a Foley catheter, a Foley catheter may merely be slide into alignment member 388 and held in place by friction or other suitable adhesive means. Preferably, the template of Figs. 42-43 is provided to the surgeon with a Foley catheter already extending through alignment member 388. Preferably, alignment member 388 is sized so as to snugly hold the Foley catheter therein. In addition, the template is provided with the Foley catheter located at the desired location.

Wing members 381 and 382 are once again provided, along with first and second guide apertures 385 and 386 therein. In order facilitate the insertion of

the tip of a suture retrieval tool through these apertures, grooves 390 are provided on the underside of each wing. Grooves 390 extend parallel to the longitudinal axis of trough 380, and preferably extend between the apertures and the front edge 393 of each wing. In this fashion, the tip of the suture retrieval tool may be slid along grooves 380 until it reaches the desired aperture. A bevel 391 is also provided on the side of the aperture adjacent grooves 390. Bevel 391 permits the retrieving end of the suture retrieval tool to be moved to a more acute angle with respect to the wing member during the retrieval process. A similar bevel 391 is provided on the upper surface of each wing member adjacent each aperture. Bevels 391 on the upper surface of the wing members extend from the opposite side of each aperture as the bevels on the under surface of the wing members. This further ensures that the retrieving end of the suture retrieval tool can be moved to an acute angle with respect to the wing members.

Finally, the template of the present invention can be manufactured of any suitable material such as polycarbonate or other FDA-approved plastic. The template may be readily molded using known technology, and is preferably manufactured as a disposable, single-use item. The drill tamper tool and anchor insertion tools, on the other hand, should be made from medical-grade stainless steel. The handles, however, may be polycarbonate or other FDA-approved plastic.

G. Alternative Anchor and Anchor-Insertion Tool

As mentioned previously, and as best shown in Fig. 19, pubic bone 12 falls away from the laparoscope at an angle of about 45° to 60°. Thus, it is impossible to create a bore in the pubic bone which extends perpendicularly from the surface of the bone. Thus, the bore produced in pubic bone 12 extends inwardly at an angle of between about 20° and about 60°. In other words, as shown in Fig. 23 which is a cross-sectional view of pubic bone 12, when bore 13 is viewed in cross-section as shown, the angle between surface 100 of the pubic bone and bore 13 at X will be between about 20° and about 60°, preferably

about 45°. During the laparoscopic surgical procedure of the present invention, the surgeon may readily modify angle X in order to provide an angle which corresponds to that of the anchor to be described (preferably about 45°). This may be accomplished by inflating or deflating the abdominal cavity as needed in order to change the angle of the laparoscopic channel in relation to the pubic bone. Since interior surface 102 of cortical bone 101 is parallel to outer surface 100 of pubic bone 12, this same angular relationship will exist within the interior of the bore. When an anchor such as that disclosed in Fig's 3 and 4 is employed, one will immediately recognize that this angular relationship of surface 102 and bore 13 will only permit the lower barb of the anchor to contact surface 102. Since cancellous (or tribecular) bone 103 offers very little support for the anchor, only the contact between the lower most barb of the anchor of Fig's 3 and 4 and surface 102 provides the principle support which prevents the anchor from being pulled out of the bore.

When anchors of the type shown in Fig's 3 and 4 are tested for pull-out strength, they are typically pulled only in the direction of arrow B. After the urethropexy procedure of the present invention is accomplished, however, any force on the anchor is most often in the direction of arrow A. As will be readily understood, due to that fact that only the lower barb will be in contact with surface 102, it is possible for the anchor to be pulled out of the bore due to forces acting in the direction of arrow A. This results from the fact that the end of the anchor to which the suture is secured is able to pivot downwardly in the direction of Arrow A since cancellous bone 103 offers little support.

In order to overcome the problems of the prior art anchor designs noted above, the present applicant has developed a new anchor design shown in Fig's 23-30. The shortcomings of the prior art are overcome by modifying the orientation of the wing members or barbs to ensure that the external ends of the wing members (i.e., the portions which contact inner surface 102 of the cortical bone) have an angular relationship corresponding to the angular relationship between bore 13 and surface 102 (to be further described in detail below). Thus,

as best shown in Fig's 24 and 25, anchor 139 comprises cylindrical body 140, at least three wing members (barbs 141, 142 and 143), and aperture 150 positioned in tab member 151. Body 140 is similar to that of the prior art designs, however distal end 160 may be rounded since it is relatively easy to urge distal end 160 into cancellous bone as needed. The conical shape of the prior art design, however, will certainly work. Proximal end 161 is preferably perpendicular to longitudinal axis 162 of body 140 to thereby provide a flat proximal end surface which may cooperate with the new anchor-insertion tool to be described herein. Aperture 150 serves the same purpose described previously (i.e., a means for attaching a suture to the anchor), and once again the surfaces and edges of aperture 150 should be as smooth as possible to prevent fraying of the suture. In fact, aperture 150 may even be highly polished or even coated to reduce friction.

Tab member 151, as shown in Fig's 24-26, preferably has a height 163 corresponding approximately to the diameter of body 140 and a width 164 less than the diameter of body 140. The length 165 of tab member 151 should be sufficient for aperture 150 to permit a size 0 suture to be passed therethrough. It is also preferred that the length of tab member 151 extend perpendicularly away from proximal end 161 to facilitate cooperation and mating with the anchor-insertion tool to be described.

As mentioned above, the most significant feature of the anchor shown in Fig's 23-30 is the arrangement of the wing member or barbs. As is the case with the prior art anchor design, the barbs may be elastically flexed (i.e., have memory) from the normal deployed position (as shown in the figures), to a compressed position. In the deployed position, the barbs preferably curvilinearly extend radially and axially away from body 140, as shown. In the compressed position, the barbs are substantially straightened to permit insertion of the anchor into a bore created in bone in the manner of the prior art (see, for example, U.S. Patent No's 5,207,679 and 5,217,486 both of which are herein incorporated by way of reference). To facilitate compression and insertion, a plurality of

channels 170 are provided along the length of body 140. One of channels 170 is positioned beneath each of the wing members, and is aligned therewith. Each of the channels is further sized so as to accept at least a portion of, and preferably the entirety of the corresponding wing member aligned therewith. In this manner, when a wing member is compressed during the anchor insertion process, the compressed and straightened wing member will be positioned entirely within channel 170 positioned adjacent the wing member.

With the wing members in this compressed state, the diameter of the anchor will be equivalent to that of body 140, thereby permitting the anchor to be inserted into a bore having a diameter only slightly greater than body 140. As the wing members extend into the bore beyond interior surface 102 of the cortical bone, the wing members will return to their deployed position, since the cancellous bone is not sufficiently hard to resist the spring-back of the wing members due to their inherent elasticity (or memory). As shown in Fig. 23, since the diameter of bore 13 is only slightly greater than body 140, the external ends of the wing members will abut against interior surface 102 thereby preventing removal of the anchor from the bore. For example, external end 144 of barb 141 is shown in Fig. 23 as resting against interior surface 102.

The cross-sectional profile of channels 170 is shown in Fig. 30, which is a cross-sectional view of the anchor of Fig. 26. As shown in this view, channels 170 are preferably sufficiently deep to permit an entire wing member to be compressed into the channel. In addition, as shown in Fig. 24, the length of each channel 170 is only sufficiently long to contain the entire corresponding wing member when the latter is compressed, Thus, channels 170 may be of different lengths depending upon the various lengths of the corresponding wing members. End 171 of channel 170 (see Fig. 24) may also be angled in relation to the longitudinal axis 162 as shown in order to correspond with the external ends of the wing members, should these external ends be angled in the manner to be described.

In order to ensure that at least a portion of the external ends of each wing member contacts interior surface 102 of the cortical bone adjacent bore 13 when bore 13 is positioned non-perpendicularly to outer surface 100 of the pubic bone, at least a portion of the external end of each wing member is aligned along first imaginary plane 175 extending through body 140 (see Fig. 25a). In the prior art anchor designs this imaginary plane is perpendicular to longitudinal axis 162, thereby evenly aligning all of the external ends of the wing members. In the anchor of the present invention, however, first imaginary plane 175 extends through said body at an angle to transverse cross-section 176 through body 140, wherein cross-section 176 is perpendicular to longitudinal axis 162. As will be understood, angle F of Fig. 25a is preferably substantially equivalent to angle X of Fig.23, thereby ensuring that at least a portion of the external end of each barb will contact interior surface 102 of the cortical bone adjacent bore 13. Thus, angle F is preferably between about 20° and about 60°, most preferably about 45°. The external ends of the wing members are more preferably tapered as shown so that the entirety of each external end will lie along first imaginary plane 175. Thus, external ends 144, 145 and 146 of corresponding barbs 141, 142, and 148 are aligned along plane 175, thereby adding further support when the anchor is secured within bore 13.

As will be more fully understood later, it is helpful at this point to also define the top of the anchor by a top-line 166 which extends along the surface of body 140 parallel to longitudinal axis 162. First imaginary plane 175 intersects top-line 166 at the point of intersection between the surface of body 140 and imaginary plane 175 which is nearest to proximal end 161. In other words, therefore, the barb extending from body 140 at point nearest to top-line 166 will also have an external end which is closest to proximal end 161. The further from top-line 166 that a barb extends from body 140, the further its external end will be from proximal end 161. The upper portion of body 40 is defined as that half of body 40 nearest to top-line 166, and the lower portion is therefore the remainder.

To provide the alignment described above, the wing members may extend from the anchor body in a number of fashions. Most preferably, however, each barb should be of a similar length in order to provide similar flexing characteristics for each barb thereby ensuring that the anchor will be urged straight into the bore. Thus, each wing member preferably extends from body 140 along a second imaginary plane extending through body 140 at an angle to cross-section 176. As will be understood, the angle between this second imaginary plane and cross-section 176 should be approximately equivalent to angle F of Fig. 25a. Alternatively, the wing members may extend from the anchor body at points equidistant from proximal end 161 (i.e., along a plane extending perpendicular to longitudinal axis 162). In order to provide the proper alignment for the external ends of the barbs, however, the length of the barbs in this embodiment would necessarily not all be equivalent to one another.

In order to provide proper support during use, various configurations and numbers of barbs may be employed. Three preferred arrangements are shown in Fig's 27-29. In the embodiment of Fig. 27, which corresponds to that of Fig's 23-26, five barbs are employed. Thus, barbs 141, 142, and 143 extend upwardly away from the upper portion of body 40, while barbs 148 and 149 extend downwardly away from the lower portion. When the anchor is viewed from the proximal end towards the distal end (Fig. 27-29), it is seen that barb 141 is substantially aligned with the top-line of body 140. To simplify the description, this will be defined as the 12 o'clock position in terms of a standard clock face. Thus, barb 141 is at about 12 o'clock, barb 142 is between about 10 and 11 o'clock, barb 143 is between about 1 and 2 o'clock, barb 149 is between about 4 and 5 o'clock, and barb 148 is between about 7 and 8 o'clock. It should be pointed out that whenever an odd number of barbs are employed, it is preferable that a greater number of barbs extend from the upper portion of the body rather than the lower portion, since further support is needed in this area.

In the embodiment of Fig. 28, three barbs (152, 153 and 154) are employed, two of which extend from the upper portion of body 140. Preferably,

barb 153 is between about 10 and 11 o'clock, barb 152 is between about 1 and 2 o'clock, and barb 154 is at about 6 o'clock. In the embodiment of Fig. 29, four barbs (155, 156, 157 and 158) are utilized, two extending upwardly away from the upper portion of body 140, and two extending downwardly away from the lower portion of body 140. Preferably, barb 155 is between about 10 and 11 o'clock, barb 156 is between about 1 and 2 o'clock, barb 157 is between about 4 and 5 o'clock, and barb 158 is between about 7 and 8 o'clock. It should be noted that any of a number of alternative configurations are possible, and the three shown are merely exemplary of the simplest and preferred embodiments.

The anchor of the present invention may be made of any of a number of materials, however titanium or titanium alloys are preferred. The anchor is also preferably singularly molded, however the wing members may be formed separately and attached to body 140 during the assembly process. For example, the wing members or barbs may be attached to body 140 in the manner described in U.S. Patent No's 5,207,679 and 5,217,486. It is preferred, however, that the barbs comprise wire-like members, and may even be formed from titanium or nickel-titanium wires in a known fashion.

As also discussed previously, aperture 150 of anchor 139 is designed so that suture 180 may pass therethrough. In this fashion, two suture tails will extend from aperture 180, and may be used in the manner previously described to elevate the periurethral tissue at the UVJ, for example. It is important during such a procedure, however, that the suture be protected from nicks and other abrasions which would compromise suture strength. While the proximal end of the anchor shown in Fig's 23-30 may be modified to that shown in Fig's 3-4 so that the anchor-insertion tool of Fig's 8-10 can be employed therewith, Applicant has developed yet another anchor-insertion tool which can be employed with the anchor design shown in Fig's 23-30. This new anchor-insertion tool not only protects the suture, it also facilitates proper alignment of the anchor within the bore and also provides a means for tensioning the suture tails in the manner shown in Fig. 20.

An anchor-insertion tool according to the present invention is shown in Fig's 31-35, and comprises a rigid elongate member 250 having:

-anchor-receiving tip 252

-hollow cylindrical intermediate portion 253 having distal end 260 adjacent anchor-receiving tip 252, intermediate portion 253 preferably having a diameter greater than the diameter of tip 252

-handle 251 attached to intermediate portion 253 at the end opposite anchor-receiving tip 252

-passageway 254 providing communication between the interior of intermediate portion 253 and the exterior of the tool

Since anchor-receiving tip 252 is also preferably hollow and its interior is in communication with the interior of intermediate portion 253, an anchor having a suture extending therefrom may be secured on tip 252, and the suture (preferably a pair of suture tails) will extend through tip 252, through at least intermediate portion 253, and through passageway 254. As shown in Fig. 31, passageway 254 is preferably provided in handle 251 and terminates on rear face 255 of handle 251. Since passageway 254 is in communication with the interior of intermediate portion 253, the suture tails may extend along the entire interior length of the tool, and exit at rear face 255 of handle 251. Thus, as shown in Fig. 32, suture tails 260 and 261 extend from anchor 139 held on tip 252, through the entire interior of the tool, and exit at rear face 255. Although the suture tails may exit from the interior of the tool at various other locations, rear face 255 provides a location convenient for the surgeon during laparoscopic urethropexy and similar procedures. In addition, the sutures are completely enclosed within the tool, and thus nicking or fraying cannot occur during the insertion process. It should be noted that the length of suture tails 260 and 261 has been shortened for purposes of clarity.

Anchor-receiving tip 252 should be structured so as to matingly engage the particular anchor being employed. In addition, as described previously, the diameter of tip 252 should be equivalent to that of the anchor body to facilitate anchor insertion. In the embodiment of Fig. 31-32, tip 252 has a slot 256

extending across the diameter of the tip and at least partially along its length, slot 256 capable or matingly receiving tab member 151 of anchor 139. Since it is critical that anchor 139 be properly aligned within the bore in the pubic bone, slot 256 prevents rotation of the anchor during the anchor insertion process. Slot 256 is preferably sized equivalent to or slightly larger than tab member 151 of anchor 139, so that tab member 151 may be placed within slot 256. Tab member 151 may be wedged within slot 256 to hold the anchor on tip 252, or alternatively, end 258 of tip 252 may be secured to proximal end 161 of anchor 139 by means of a releasable adhesive. Any FDA-approved epoxy or other adhesive may be employed, as long as the bond between end 258 and proximal end 161 may be readily broken after the anchor has been seated within the bore merely by pulling the insertion tool away from the bore. In addition, since the suture tails are preferably tensioned between the anchor and handle 251 in a manner to be described, suture tails 260 and 261 will also act to keep tab member 151 held in place in slot 256.

As best shown in the cross-sectional views of Fig's 33-34, the wall thickness of tip 252 should be such that suture 180 which extends through aperture 150 of the anchor tab member will not be compressed by the interior walls of tip 252 when the anchor is in place on tip 252. In other words, the interior diameter of anchor-receiving tip 252 is greater than the sum of the width of tab member 151 plus twice the diameter of suture 180. In this manner, suture 180 will be further spared from damage during the anchor insertion process.

As will be apparent, in order to properly seat anchor 139, anchor-receiving tip 252 should have a length sufficient to ensure that all of the barbs of the anchor are inserted past the cortical bone for proper barb deployment. Since it is preferred that proximal end 161 of anchor 139 be approximately aligned with interior surface 102 of the cortical bone surrounding the bore when the anchor is properly seated within a bore (i.e., external ends of all barbs resting against interior surface of cortical bone), it will be apparent that anchor-receiving tip 252 should have a length approximately equivalent to, or slightly greater than the

thickness of the cortical bone (between about 5 mm and about 8 mm). End 260 of intermediate portion 253 not only acts to drive the anchor into the bore, but also acts as a stop since its diameter is preferably greater than the anchor body and the bore into which it is being inserted. Thus, the proper length for tip 252 will ensure not only that the anchor is driven sufficiently deep within the bore to fully deploy all of the barbs, but also to ensure that the anchor is not driven too far into the bore. In the latter situation, anchor stability may be compromised, and the suture may be damaged by the edges of the bore once the surgical procedure has been completed.

In order to facilitate manipulation of the anchor-insertion tool within the laparoscope, a plurality of ridges 259 are preferably provided about the circumference of intermediate portion 253. Ridges 259 are preferably positioned adjacent handle 151, most preferably between about 5 cm and about 10 cm from the handle. Since the diameter of intermediate portion 253 is preferably slightly smaller than the diameter of the laparoscope to be employed (preferably 7.8 mm and 8.0 mm respectively), ridges 259 will assist in controlling the insertion tool during the procedures of the present invention. Preferably, ridges 259 are sized so as to cooperate with the standard rubber grommet of a laparoscope.

Handle 252 may be secured to intermediate portion 253 by any of a number of means, however it is preferable that handle 252 be threadably secured to intermediate portion 253. Thus, corresponding male and female threads are provided on the handle and the intermediate portion. Once again handle 251 preferably has curved hand grip surfaces . In this embodiment, however, handle 251 preferably has dissimilar top and bottom portions 271 and 272, respectively. If anchor 139 is secured to tip 252 such that the top-line of the anchor is aligned with top portion 271 of handle 251, the surgeon can readily ensure that the anchor will be properly inserted into the bore. As long as top portion 271 extends directly upwardly during anchor insertion, proper placement will be guaranteed. In order to facilitate alignment, bottom portion 272 of handle 251 is preferably significantly heavier than top portion 271. This weight

differential will further guarantee alignment, since gravity will cause the insertion tool to rotate within the laparoscopic channel to the correct position. It should be appreciated, however, that this alignment means (i.e., and oriented handle) requires that the engagement of handle 251 with intermediate portion 253 be precise. Of course other alignment means may be provided, such as guide lines, leveling bubbles, and the like.

As mentioned previously, providing tension in the suture tails extending from the anchor will not only help in maintaining the anchor on anchor-receiving tip 252, but will also assist during the suture retrieval step shown in Fig. 20 (i.e., when the insertion tool has been partially removed from the laparoscopic channel). Proper tensioning can be achieved by means of at least one notch into which the suture tail(s) may be wedged. Preferably, the notch(es) are positioned adjacent said passageway so that the suture tails may extend through the passageway directly into the notch(es). Thus notches 280 and 281 are preferably provided on rear face 255 of handle 251. In fact, passageway 254 preferably exits handle 251 in an elongated diamond-shaped exit 279, and thus notches 280 and 281 may comprise the opposing narrow corners of exit 279 as shown. When suture tails 260 and 261 leave passageway 254 through exit 279, each tail may be wedged within notches 280 and 281, respectively. In this manner, the tails will be tensioned between notches 280 and 281 and aperture 150 of the anchor. After the anchor has been inserted into the bore, and as the insertion tool is pulled partially out of the laparoscopically channel, suture tails 260 and 261 will slide within their respective notches, thus maintaining the desired tension in the suture tails as needed for the suture retrieval step. To further enhance the tensioning of the sutures, passageway 254 may taper from intermediate portion 253 towards exit 279, thereby providing an additional wedging of the suture tails within the final portions of passageway 254.

It should be noted that intermediate portion 253 preferably has a length of between about 52 cm and about 55 cm to facilitate its use through a laparoscope.

To facilitate a quick and proper anchor insertion process, anchor 139 and the anchor-insertion tool of the present invention may be provided to the surgeon in the loaded form of Fig. 32 (with suture attached and wedged for tensioning as shown). The anchor may even be releasably adhered to the anchor-receiving tip as shown. In this manner, the surgeon can merely open a sterile surgical kit containing preferably two pre-loaded insertion tools (i.e., anchor 139 engaged with anchor-receiving tip and suture tensioned between anchor and notches on handle 251). The pre-loaded insertion tools are sufficiently inexpensive to permit one-time use, or the manufacturer could provide a credit for the return of used anchor-insertion tools which can be sterilized and re-loaded. The surgical kit for performing laparoscopic urethropexy can also include a drill tamper tool, a suture retrieval tool, and/or one or more variously-sized templates (all of which have been described previously). In this fashion, the surgeon will have all of the tools necessary for a quick and simple urethropexy within a small sterile kit.

H. <u>Additional Embodiment for Anchor-Insertion Tool</u>

Figures 37-41 depict yet another embodiment for the anchor-insertion tool of the present invention. The anchor inserter of Figs. 37-41 is similar in some respects to that shown in Fig's 8-10. The principle differences are the elimination of an intermediate portion, a lengthening of the grooves, and the positioning of a depression adjacent to the tip. As will be understood shortly, these modifications are significant and provide a considerable advantage over the previously-disclosed design.

The anchor-insertion tool of Fig's 37-41 comprises an elongate shaft 358 having a handle 351 at its proximal end, and an anchor-receiving tip 352 at its distal end. Handle 351 may be provided in any of a variety of shapes, and that shown is merely one possibility. Handle 351 may be secured to shaft 358 by means of threading, glue or other means well-known to those skilled in the art. Additionally, handle 351 may be plastic, wherein the remainder of the insertion tool is preferably stainless steel, or other appropriate material.

Anchor-receiving tip 352 is preferably similar to that shown in Figs. 8-10, which in turn is similar to that shown in Fig's 4-6 of U.S. Patent No. 5,207,679. Thus, anchor-receiving tip 352 is constructed so as to matingly receive anchor 9 of Fig's 3-4. Anchor-receiving tip 352 is cylindrical in nature, having a diameter approximately equivalent to body 40 of anchor 9. In this manner, at least a portion of anchor-receiving tip 352 may pass into the bore in the pubic bone during the anchor insertion process in order to properly seat the anchor completely within the bore.

Anchor-receiving tip 352 has a pair of guide tabs 353 extending from the end of anchor-receiving tip 352 on either side thereof. Guide tabs 353 are sized and shaped so as to be matingly received within the corresponding grooves on anchor 9. Anchor-receiving tip 352 also has a cylindrical slot 354 aligned with the longitudinal access of tip 352. Cylindrical slot 354 should correspond in size and shape to the cylindrical end of anchor 9 in order to matingly receive the same. Guide tabs 353 and slot 354 preferably apply a compressive force against anchor 9 in the manner previously described in order to hold anchor 9 on tip 352.

In order to protect the suture tails extending from anchor 9 during the anchor insertion process, a pair of grooves 355 are provided on either side of the anchor-insertion tool, and extend from tip 352 at least partially along the length of shaft 358 as shown. As compared to the previous insertion tool design, however, grooves 355 extend along a considerable portion of the length of shaft 358. In fact, grooves 355 preferably have a length sufficient to insure that the entire length of each suture tail is positioned within one of the grooves. In other words, when an anchor 9 having a suture extending therefrom is positioned on anchor-receiving tip 352, a suture tail may be placed entirely within each of grooves 355 with the suture terminating prior to end 402 of groove 355 (Fig. 37).

As best shown in Fig 40, grooves 355 also preferably taper in the manner described previously. On tip 352, grooves 355 should be sufficiently deep to

ensure that the suture does not extend above the surface of the tip. In other words, the sutures will be completely hidden within the grooves along anchor-receiving tip 352. A distal depression 359 is provided adjacent tip 352, and grooves 355 preferably begin to taper outwardly just prior to distal depression 359. Although grooves 355 should be at least as deep (as measured from the surface of the shaft 358) as the diameter of the suture, the depth of grooves 355 in the region of depression 359 should be such that a portion of the suture tails will pass through depression 359. In this manner, an O-ring or other retaining band may be secured about depression 359 in order to slidably hold the suture tails within grooves 355. Grooves 355 continue to taper outwardly beyond distal depression 359, and thus, the distance A between grooves 355 will increase. This provides additional strength and rigidity to shaft 358.

The anchor-insertion tool of Fig's 37-41 also has one or more depressions 360 which extend about the circumference of shaft 358 and intersect grooves 355 as shown. Depressions 360 are sized to accommodate a retaining band, such as O-rings 361, in order to slidably hold the suture tails within grooves 355. Thus, depressions 360 should have a depth less than that of grooves 355. Grooves 355 in the region of depressions 360 should also be sized such that the O-rings 361 may compressively and slidably hold the suture tails within grooves 355. Therefore, the difference in depth between grooves 355 and depressions 359 and 360 should be less than the diameter of the suture. A suture positioned within 355 will thus be slidably held between O-rings 361 and grooves 355. In this manner, the anchor insertion method previously described can be readily accomplished with the anchor-insertion tool of Fig's 37-41, wherein tension is applied to the suture tails when the insertion is removed from a bore within which the anchor has been secured.

In the embodiment shown in Fig's 37-41, the retaining bands, or O-rings 361, may be sized such that they act as a grommet during the anchor insertion process. In other words, after anchor 9 has been loaded upon the anchor-insertion tool, the tip of the tool is inserted through a cannula (such as the

operative channel of a laparoscope) in order to present anchor 9 to the bore into which it will secure. Shaft 358 is preferably only slightly smaller in diameter than the interior diameter of the cannula, and O-rings 361 may extend above the surface of shaft 358. O-rings 361 may therefore act as a grommet within the cannula (e.g. the operative channel of a laparoscope), thereby preventing the escape of insufflation gas from the interior of the patient. Furthermore, O-rings 361 provide additional stability because of the tight fit within the operative channel of the laparoscope.

In the presently preferred embodiment, O-rings 361 preferably are sized so that they do not extend substantially above the surface of shaft 358. Although such a configuration lessens or eliminates any sealing effect caused by the O-rings, applicant has found that sealing may also be provided by the interaction of a seal placed on the end of the cannula with shaft 358. Such seals are well-known in the art, and are commonly employed for this purpose. Additionally, since the suture tails are carried entirely within grooves 355, a relatively tight fit between shaft 358 and the cannula may be maintained, thereby further lessening the escape of insufflation gas. Furthermore, end 402 of grooves 355 is located well ahead of handle 351, preferably at a distance sufficient to ensure that during the normal insertion process grooves 355 (and hence the suture tails present therein) will remain entirely within the patient or the cannula. In this fashion, grooves 355 will not permit insufflation gas to escape from the interior of the patient.

Often it is difficult for a surgeon to thread sutures into needles and the like while performing surgical procedures, particularly because of the difficulties caused by surgical gloves. In order to alleviate such problems, applicants have also developed a unique method for threading the sutures onto the anchor-insertion tool. As best shown in Fig. 41, a pair of suture threaders 400 are pre-loaded on the anchor-insertion tool. Similar suture threaders are employed for threading surgical needles and the like. In the present case, each suture threader 400 comprises a length of wire which is bent at its middle to form a loop

401. The opposite ends of the threader are then secured to a pull tab (or handle) 357. In the present case, both suture threaders are preferably connected to a single pull tab 357 as shown. Each suture threader is inserted into one of the grooves 355 as shown, with its loop 401 extending beyond and adjacent tip 352. At its opposite end, each threader preferably extends beyond end 402 of grooves 355 such that pull tab 357 may be readily accessed. O-rings 361 are then secured about the anchor-insertion tool within depressions 359 and 360. This results in each suture threader being slidably held within one of grooves 355 beneath O-rings 361 as shown.

In order to utilize the suture threaders, an anchor is first secured on top tip 352. Since tip 352 will orient the anchor in a pre-determined manner, loops 401 of the threaders as shown in Fig. 41 will align with aperture 43 on anchor 9. In this manner, the surgeon or other medical personnel may simply thread the suture straight through one of loops 401, aperture 43 on anchor 9, and thereafter through the second loop 401. Once threaded, the suture is centered within aperture 43, and then pull tab 357 is grasped. As pull tab 357 is retracted in the direction of handle 351 away from grooves 355, the suture tails will be pulled into grooves 355 by loops 401. As the surgeon continues to retract pull tab 357, the sutures are threaded into grooves 355 beneath O-rings 361, thereby loading the suture onto the device in the proper manner. Thus, the suture threaders provide a convenient way for the surgeon to prepare the anchor-insertion tool for the surgical procedures of the present invention.

As discussed previously, after anchor 9 has been secured within a bore in the pubic bone, the anchor-insertion tool can be retracted away from the anchor by means of handle 351. When the insertion tool is retracted in this way, the suture tails will slide between O-rings 361 and grooves 355 such that the suture tails will extend between the anchor and the tool after this retraction step. The tool should not be completely withdrawn at this point, however, since the suture tails should be permitted to extend between the tool and the anchor in order to allow suture retrieval as shown in Fig. 20. It is also preferred that the

suture tails and grooves 355 be sufficiently long so that the insertion tool can be retracted as shown in Fig. 20 while ensuring that the suture remains beneath all of the O-rings 361. In this manner, the suture tails will be controlled and the barbs of the anchor will be deployed by means of the tensioning of the suture tails. In addition, this insures that the O-rings 361 will remain within the cannula or operative channel of the laparoscope for sealing purposes, if any. Finally, shaft 356 also terminates in distal end 358 which is shown as being tapered. The tapering of distal end 356 provides improved laparoscopic vision during the insertion process. In addition, tapered distal end 356 acts as a stop during the anchor insertion process, thereby insuring that the anchor is inserted to the proper depth.

In the embodiment shown in Fig's 36-38, anchor-receiving tip 352 once again preferably has a length sufficient to insure proper anchor depth. Since anchor-receiving tip 352 preferably has a diameter equivalent to that of anchor 9, which in turn is only slightly smaller than the bore in the pubic bone, distal end 356 acts as a stop during the insertion process. Therefore, the length of anchor-receiving tip 352 should be approximately equal to the depth of the bore minus the length of the anchor. Shaft 358 should be of a length sufficient to permit the tool to be effectively employed through a laparoscope. Thus, shaft 358 has a length of between about 45 and about 60 cm, preferably between about 50 and about 52 cm. The length of the grooves should be sufficient ensure that the entire length of both suture tails can be positioned entirely within one of the grooves, while also ensuring that the grooves remain either within the abdominal cavity or within the operative channel of the laparoscope when the insertion tool is partially retracted as shown in Fig. 20. This ensure that insufflation gas cannot escape through the grooves. Preferably, the grooves between about 25 cm and about 30 cm from the tip. While it is preferred that a at least one depression be positioned adjacent the tip, any number of additional depressions may be provided anywhere along the length of the shaft. Two or three additional depressions 360 are preferred as shown in the accompanying drawings.

Figure 49 depicts an alternative embodiment of an anchor 509 which may used in the methods of the present invention. Helical anchor 509 is configured for securing one or more sutures to tissue, such as Cooper's ligament. Cooper's ligament (also referred to as the iliopectineal ligament) is identified at 11 in Fig. 22. Thus, one or more anchors 509 may be secured to Cooper's ligament, and sutures extending from the anchors may be used to elevate the patient's urethra in the manner described previously. In other words, the tissue adjacent the patient's vagina (e.g., the periurethral tissue) is suspended from Cooper's ligament, rather than the pubic bone.

In the embodiment shown in Fig. 49, helical anchor 509 comprises a helical portion 540 having a point 544 at its distal end. Helical portion 540 generally comprises a series of continuous helical coils, and may be collapsible and/or expandable in the longitudinal direction. Any number of coils may be provided on helical portion 540, and that shown is merely exemplary. In fact, helical portion 540 may be configured similarly to any of the helical fasteners described in U.S. Patent No. 5,810,882 ("the '882 patent"), which is incorporated herein by way of reference.

Anchor 509 may be inserted into tissue by rotatingly urging helical portion 540 into the tissue, and the proximal end of anchor 509 (i.e., the end opposite point 544) is preferably configured to facilitate the insertion of helical portion 540 into tissue. The proximal end of anchor 509 may be configured in accordance with any of the various structures described in the '882 patent. Alternatively, and as shown in Fig. 49, the proximal end of anchor 509 may comprise a loop portion 543 which not only facilitates the insertion of anchor 509 into tissue (such as Cooper's ligament) but also provides an aperture through which a suture may be inserted. Of course it is also contemplated that a suture may be attached to anchor 509 in a variety of other manners, such as merely tying the suture to a portion of anchor 509.

Helical anchor 509 may be made from any of variety of semi-stiff, metallic wire, such as titanium, stainless steel, or nitinol, as further described in the '882 patent. In addition, loop portion 543 may be integrally formed from the same wire used to form helical portion 540. Thus, one end of the wire material may be wound into a helical shape to provide helical portion 540, and the other end bent into a loop so as to form loop portion 543. Of course it is also contemplated that anchor 509 may be formed from a variety of other materials, and in a variety of other manners (e.g., injection molded from plastic). Point 544 provided on the distal end of helical portion 540 is preferably sharp in order to facilitate penetration of helical portion 540 into tissue.

Loop portion 543 provides a central aperture 547 through which a suture 510 may be threaded (see Fig. 49). In this fashion, when suture 510 is threaded through aperture 547, two suture tails will extend from anchor 509. These suture tails may be used, for example, in the manner previously described to elevate the periurethral tissue at the UVJ. Of course it is also contemplated that suture 510 may be attached to anchor 509 in a variety of other manners, such as tying the suture to a portion of anchor 509 or providing a separate eyelet on anchor 509 suitable for threading a suture therethrough. The distal end of loop portion 543 may be fused, welded or otherwise adhered to a portion of anchor 509, such as to the proximal end of loop portion 543 at 542. In this manner, loop portion 543 comprises a closed loop which prevents suture 510 threaded through aperture 547 from escaping. Of course suture 510 will still be able to slide within aperture 547, similar to the manner in which a sewing thread slides within the eyelet of a needle.

Anchor 509 may be secured to tissue (such as Cooper's ligament) by rotatingly urging helical portion 540 into tissue. Thus, sharp point 544 of the distal end of helical portion 540 may be urged against tissue as anchor 509 is rotated. As anchor 509 is rotated, the helical coils of helical portion 540 will enter the tissue, thereby securing anchor 509 in the tissue. The penetration depth of anchor 509 will depend upon the length of helical portion 540, as well

as the number of anchor revolutions during the insertion process. Preferably, helical portion 540 has a length of between about 2 and about 10 mm, and has between about 2 and about 6 helical coils. It is also preferred that anchor 509 be rotated a sufficient number of revolutions during insertion to ensure that at least about one half of, and more preferably substantially the entirety of helical portion 540 is urged into the tissue (i.e., so that only loop portion 543 does not penetrate the tissue).

As mentioned previously, the proximal end of anchor 509 is preferably configured to facilitate the insertion of helical portion 540 into tissue (such as by rotatingly urging the distal end of helical portion 540 into tissue). For example, the proximal end of anchor 509 may be configured such that a grasping device may be used to grasp the proximal end of the anchor, and rotatingly urge the helical portion of the anchor into tissue. In the embodiment shown in Fig. 49, loop portion 543 is provided at the proximal end of the anchor, and may have a diameter 546 which is greater than the diameter 545 of helical portion 540. It should be pointed out, however, that helical portion 540 may be tapered such that its diameter varies along its length. In such an embodiment, the diameter of loop portion 543 should be greater than the maximum diameter of helical portion 540. In addition, as best seen in Fig. 53, loop portion 543 is positioned substantially normal to helical portion 540. In other words, loop portion 543 lies in a plane which is substantially normal to a tubular cross-sectional plane of helical portion 540. Of course other configurations of anchor 509 may be employed, and that shown is merely exemplary of one embodiment according to the present invention.

While loop portion 543 may be grasped with a surgical grasping device in order to rotatingly urge helical portion 540 of anchor 509 into tissue, the present invention also provides an anchor-insertion tool configured for inserting anchor 509 into tissue. The anchor-insertion tool may even be configured for laparoscopically inserting anchor 509 into tissue, such as through the operative channel of the laparoscope itself. The anchor-insertion tool used with anchor

509 can be used in the same manner as the anchor-insertion tools previously described herein, except for the fact that helical anchor 509 is urged into tissue (such as Cooper's ligament) rather than the pubic bone.

Figure 50 is a cross-sectional view of an anchor-insertion tool which may be used to insert a helical anchor into tissue, and Fig. 51 is a plan view the distal end of the tool shown in Fig. 50. The anchor insertion tool of Fig. 50 comprises a rigid elongate member 550 having an anchor-receiving tip 552 at its distal end, and a tissue dissection pad 551 at its proximal end. As more fully described below, pad 551 may be used during an urethropexy procedure for tissue dissection. Alternatively, pad 551 may be replaced by a handle (such as any of the various handles previously described herein for use with an anchor-insertion tool). However, since the insertion of helical anchor 509 into soft tissue (such as Cooper's ligament) generally requires less force than inserting an anchor into the patient's pubic bone, dissection pad 551 may be readily used in place of a handle on the proximal end of the anchor-insertion tool shown in Fig. 50. The anchor-insertion tool of Fig. 50 may be made from the same types of materials discussed above for the other embodiments of anchor-insertion tools. In addition, the dimensions may be similar those previously discussed herein.

Anchor-receiving tip 552 includes a cylindrical chamber 557 having a bottom wall 553. Chamber 557 is sized and configured to accommodate helical anchor 509 therein, preferably such that sharp point 544 of the anchor will not protrude beyond distal end 556 of the anchor-insertion tool. The diameter of chamber 557 may be slightly greater than diameter 545 of helical portion 540 of anchor 509, thereby limiting side-to-side play of anchor 509 when the anchor is positioned within chamber 557. A pair of slots 554 may also be provided, and extend radially away from chamber 557, on opposite sides thereof. Slots 554 also extend lengthwise the entire length of chamber 557 between distal end wall 556 of elongate member 550 and bottom wall 553 of chamber 557. Slots 554 are sized and configured to slidingly receive loop portion 543 of anchor 509 therein.

Figures 52 and 53 depict a loaded anchor-insertion tool, with anchor 509 positioned within chamber 557 of the anchor-insertion tool. As noted in Fig. 52, anchor 509 may be housed completely within the anchor-insertion tool, such that sharp point 544 does not protrude beyond distal end 556 of the anchor-insertion tool. The helical portion of anchor 509 is located between the side walls of chamber 557, while the outer extremities of loop portion 543 are positioned within slots 554. Preferably, slots 554 are sized so as to limit any side-to-side play of loop portion 543 therein. In this manner, when the anchor-insertion tool is rotated, slots 554 ensure that anchor 509 will rotate therewith. In other words, slots 554 ensure that anchor 509 cannot rotate with respect to the anchor-insertion tool.

In order to insert anchor 509 into tissue, anchor 509 is first loaded into chamber 557 of the anchor-insertion tool in the manner shown in Fig. 52. Distal end 556 of the anchor-insertion tool is then urged against the tissue into which anchor 509 is to be inserted. If distal end 556 is urged against the tissue with sufficient force, a portion of the tissue will be urged into chamber 557 such that sharp point 544 will penetrate the tissue. Thereafter, the anchor-insertion tool is then rotated such that helical portion 540 of anchor 509 will be rotatingly urged into the tissue. As the anchor-insertion tool is rotated, anchor 509 will advance into the tissue in the direction of the arrow shown in Fig. 52, with loop portion 543 sliding within slots 554 of the anchor-insertion tool.

It should be pointed out that chamber 557 may also be sized such that sharp point 544 and at least part of helical portion 540 of anchor 509 extends beyond distal end 556 of the anchor-insertion tool. In this manner, bottom wall 553 of chamber 557 may be used to further urge anchor 509 into the tissue. Bottom wall 553 will apply force to loop portion 543 in a direction parallel to the longitudinal axis of the anchor (i.e., in the direction of the arrow shown in Fig. 52), until the region of helical portion 540 originally extending beyond distal end wall 556 of the anchor-insertion tool has penetrated into the tissue.

Although a suture may be attached to helical anchor 509 after the anchor has been inserted into tissue, it is preferred that suture 510 be threaded through loop portion 543 of anchor 509 prior to inserting the anchor into tissue. As was the case with the previously described embodiments, it is also desirable to control the sutures during the anchor insertion process, particularly so that they may be later retrieved using a suture retrieval tool according to the present invention. In order to provide such suture control, any of the previously-described anchor-insertion tools may be used (provided that suitable modifications are made to the anchor-receiving tip in order to accommodate helical anchor 509). For example, anchor-receiving tip 552 of Fig. 50 may be provided on an anchor-insertion tool shown in Figs. 8, 31, or 37.

Alternatively, as best shown in Fig. 50, the anchor-insertion tool may include a lumen extending through the interior of the anchor-insertion tool, preferably along its longitudinal axis. While elongate member 550 may be hollow (thus providing a lumen therein), the internal lumen may be provided by a bore 555. Bore 555 is preferably sized to accommodate both of the suture tails extending away from loop portion 543 of the anchor, as shown in Fig. 52. Bore 555 may extend from bottom wall 553 of chamber 557 through the entire length of the anchor-insertion tool, or, as shown in Fig. 50, until cylindrical cavity 558 (which is provided to accommodate dissection pad 551). By extending bore 555 through the entire length of the anchor-insertion tool, insertion of the suture tails therein will be simplified (e.g., by threading the suture tails through bore 555 with a stiff wire). As mentioned previously, the cross-sectional size and shape of bore 555 should be chosen to accommodate a pair of suture tails extending away from loop portion 543. Preferably, the fit of the suture tails within bore 555 is somewhat snug such that the suture tails may be tensioned between anchor 509 and the anchor-insertion tool once the anchor has been inserted into tissue (e.g., in a manner similar to that shown in Fig. 20) to facilitate suture retrieval into the patient's vagina.

A suture 510 threaded through loop portion 543 of anchor 549 should also have a sufficient length such that after anchor 509 has been inserted into tissue and the anchor-insertion tool of Fig. 50 withdrawn away from the anchor, a portion of each tail of suture 510 will remain within the anchor-insertion tool in a manner similar to that shown in Fig. 20. The suture tails may then be retrieved into the vagina in the same manner as shown in Fig. 20.

Figures 54-56 depict an alternative embodiment of an anchor-insertion tool for use with helical anchor 509. This embodiment generally comprises an elongate member 650 having an anchor-receiving tip 652 at its distal end. The proximal end of the anchor-receiving tool shown in Figs. 54-56 may be configured similar to that shown in Fig. 50 (i.e., having a dissection pad 551) or may include any of the various handle embodiments described previously. A pair of slots 654 once again extend radially away from cylindrical chamber 657 on opposite sides thereof. However, in the embodiment of Figs. 54-56, slots 654 extend through the entire wall of anchor-receiving tip 652 to the exterior surface of the anchor-receiving tool. Once again chamber 657 may be sized such that an anchor 509 inserted therein will not extend beyond distal end wall 656, and loop portion 543 of the anchor will be positioned adjacent or even against bottom wall 653 of chamber 657.

Rather than positioning the suture within a bore extending through the anchor-insertion tool, the embodiment of Figs. 54-56 allows the suture to extend along the exterior surface of the anchor-insertion tool, similar to the embodiments described previously (e.g., Fig 8). Although the suture tails may be held against the outer surface of the anchor-insertion tool by hand, one or more elastic bands 661 (see Fig. 56) may be used to hold suture 510 against the exterior surface of the anchor-insertion tool. Any number of elastic bands may be employed, and shouldered depressions of the type shown, for example, in Fig. 8 at 59 and 60, may be provided along the anchor-insertion tool such that one or more elastic bands may be held within the shoulder depressions as

described previously. The elastic bands will help to control the suture tails, as previously described herein.

The anchor-insertion tool of Fig. 50 may include a dissection pad 551 at its proximal end. Dissection pad 551 may comprise any of a variety of materials suitable for use in dissecting tissue, particularly flexible materials such as rubber. Preferably, and as shown in Fig. 50, pad 551 comprises a flexible, absorbent material such as , such as a woven or non-woven absorbent material (e.g., woven cotton). A cylindrical cavity 558 may be provided at the distal end of elongate member 550, and absorbent pad 551 may include a cylindrical extension 559 sized to fit snugly within cavity 558. In this manner, pad 551 may be secured to the proximal end of the anchor-insertion tool by securing cylindrical extension 559 within cavity 558 such as by means of an adhesive, or by crimping the walls of cavity 558 (e.g., in a manner similar to that by which an eraser is secured to a pencil). Absorbent pad 551 may be formed from a narrow strip of woven cotton which has been tightly rolled into a cylindrical structure, thus providing a somewhat stiff "Kittner sponge" similar to those currently employed by surgeons. In fact, absorbent pad 551 may be formed in any of the variety of manners in which Kittner sponges are formed. Of course, a variety of other configurations for absorbent pad 551 may be employed, all of which are within the scope of the present invention.

Absorbent pad 551 may be employed for blunt dissection during an urethropexy procedure. For example, absorbent pad 551 may be used to dissect the space of Retzius 8, as described previously, prior to insertion of one or more helical anchors into tissue (such as into Cooper's ligament). Blunt dissection using absorbent pad 551 may be used in place of the balloon dissection described previously herein, or may be used in conjunction with balloon dissection. Thus, the anchor-insertion tool of Fig. 50 provides for not only insertion of a helical anchors, but also for blunt dissection prior to anchor insertion.

An urethropexy procedure using the helical tissue anchor shown in Fig. 49 and the anchor-insertion tool of Figs. 50 or 54 may be performed similarly to the procedures described above. However, since the helical anchor is inserted into tissue, rather than bone, there is no need to create any type of bore in the pubic bone of the patient. Rather, one or more anchors 509, each having a suture threaded through loop portion 543 of the anchor (as shown in Fig. 49), is inserted into Cooper's ligament in the manner described above. Preferably, a single helical anchor 509 is inserted into each of the patient's Cooper's ligaments 11 (see Fig. 22).

Once an anchor has been secured within Cooper's ligament, the anchor-insertion tool is withdrawn a short distance away from Cooper's ligament such that each suture tail of suture 510 will extend between anchor 509 and the anchor-insertion tool (similar to that shown in Fig. 20). Thereafter, each suture tail may be retrieved into the vagina using the suture retriever described previously. In addition, a template of the type described previously herein may be used to guide proper suture placement in the periurethral tissue. Once both suture tails have been retrieved into the vagina, the suture tails may be tied in the same manner as before. Excess suture is then cut, such as by using the device shown and described in U.S. Patent No. 5,860,993.

It should be pointed out that the anchor-insertion tools shown in Figs. 50 and 54 may be used laparoscopically to insert a helical anchor into Cooper's ligament, such as through the operative channel of a laparoscope. Alternatively, these anchor-insertion tools, as well as the helical anchors associated therewith, may be used in an open procedure, or in an mini-laparotomy procedure. In a mini-laparotomy procedure, the anchor-insertion tool is inserted through a small incision, rather than through the operative channel of the laparoscope.

The foregoing description of preferred embodiments is by no means exhaustive of the variations of the present invention which are possible, and has thus been presented only for purposes of illustration and description. These

modifications and variations will be apparent to those skilled in the art in light of the teachings of the foregoing description, and these modifications and variations are well within the scope of the present invention. For example, the anchor-insertion tools of the present invention may be used with any of a variety of anchor types, provided that the anchor-receiving tip is modified accordingly. For example, the anchor-receiving tip of the tool shown in Fig's 36-38 herein may be modified to correspond with that shown in U.S. Patent No. 5,100,417, thereby permitting the use of the anchor of this patent with the insertion tool of the present invention. Similar modifications to anchor-receiving tip 352 would enable one to use various other types of anchors, and such modifications are well-within the scope of the present invention. Thus, it is intended that the scope of the present invention be defined by the claims appended hereto, and not by the specific embodiments shown in the drawings.

What we claim is:

1. A helical anchor for attaching a suture to tissue, comprising:

(a) a helical portion comprising a plurality of helical coils, and having proximal and distal ends; and

(b) a loop portion at the proximal end of said helical portion.

2. The helical anchor of claim 1, wherein the diameter of said loop portion is greater than the diameter of said helical portion.

3. The helical anchor of claim 1, wherein said loop portion is substantially normal to said helical portion.

4. An anchor-insertion tool for securing an anchor to a structure within a patient's body, comprising an elongate shaft having distal and proximal ends, an anchor-receiving tip at said distal end, and a flexible dissection pad at said proximal end.

5. The anchor-insertion tool of claim 4, wherein said anchor-receiving tip comprises a chamber for receiving an anchor therein.

6. The anchor-insertion tool of claim 5, wherein said anchor-receiving tip further includes at least one slot extending radially away from said chamber.

7. The anchor-insertion tool of claim 6, wherein said anchor-receiving tip includes a pair of said slots extending radially away from opposite sides of said chamber.

8. The anchor-insertion tool of claim 4, further comprising a lumen extending at least partially through the interior of said shaft.

9. The anchor-insertion tool of claim 4, wherein said dissection pad is absorbent.

10. A loaded anchor-insertion tool, comprising, in combination, the anchor-insertion tool of claim 4, and a helical anchor engaged with said anchor-receiving tip.

11. The loaded anchor-insertion tool of claim 10, further comprising a suture extending away from said anchor.

12. A surgical method for securing an anchor in a patient, comprising:

(a) providing the anchor-insertion tool of claim 4;

(b) inserting the proximal end of said anchor-insertion tool into the patient;

(c) dissecting tissue away from an anchoring site using said dissection pad

(d) removing said anchor-insertion tool from the patient;

(e) inserting the anchor-receiving tip of said anchor-insertion tool into the patient, said anchor-receiving tip having an anchor loaded thereon or therein; and

(f) securing said anchor in the patient at said anchoring site by manipulating said anchor-insertion tool.

13. The surgical method of claim 12, further comprising the step of providing a suture, said suture extending away from said anchor.

14. The surgical method of claim 12, wherein said anchor comprises a helical tissue anchor, and further wherein said anchor is secured in the patient by rotatingly urging said anchor into soft tissue.

15. The surgical method of claim 14, wherein said anchor is secured to Cooper's ligament, and further comprising the step of supporting the patient's urethra using said suture.

16. A surgical method for treating urinary incontinence, comprising:

(a) securing a suture within a patient's body by a helical anchor;

(b) retrieving a portion of said suture into the patient's vagina; and

(c) supporting the patient's urethra using said suture.

17. The surgical method of claim 16, further comprising the step of securing said helical anchor to Cooper's ligament.

18. The surgical method of claim 16, further comprising the step of securing said helical anchor to Cooper's ligament under laparoscopic vision.

19. The surgical method of claim 17, wherein said helical anchor is secured to Cooper's ligament through the operative channel of a laparoscope.

20. The surgical method of claim 16, wherein a pair of tails of said suture extend away from said anchor, and wherein said step of retrieving a portion of said suture into the patient's vagina comprises snaring one of said tails with the retrieving end of a suture retriever vaginally inserted into the patient's body, and thereafter withdrawing said retrieving end into the patient's vagina so as to retrieve said tail into the vagina.

21. The surgical method of claim 20, wherein each of said suture tails is separately retrieved into the patient's vagina, and wherein the step of supporting the patient's urethra using said suture comprises securing said suture to the periurethral tissue adjacent the urethra by tying said tails to one another within the vagina.

22. The surgical method of claim 20, wherein said helical anchor has an aperture through which said suture extends such that said pair of suture tails extend away from said anchor.

23. A surgical method for elevating a patient's urethra in order to treat urinary incontinence, comprising:

(a) inserting a laparoscope into a patient;

(b) securing a helical anchor to Cooper's ligament within the patient under laparoscopic vision; and

(c) suspending the periurethral tissue adjacent the patient's urethra from said anchor, thereby elevating the urethra to the desired angle;

wherein the periurethral tissue is suspended from said anchor by a suture.

Fig. 1

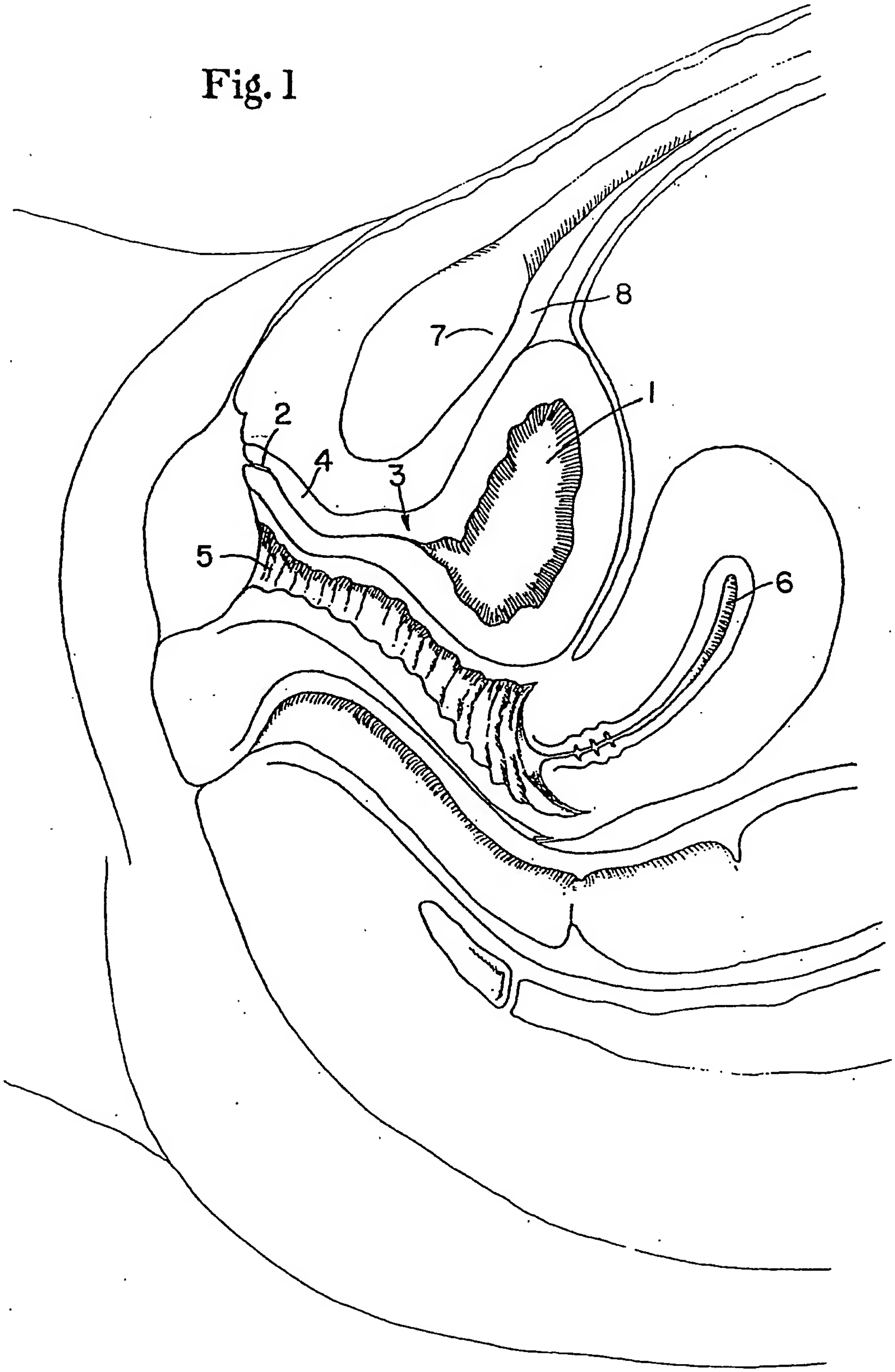
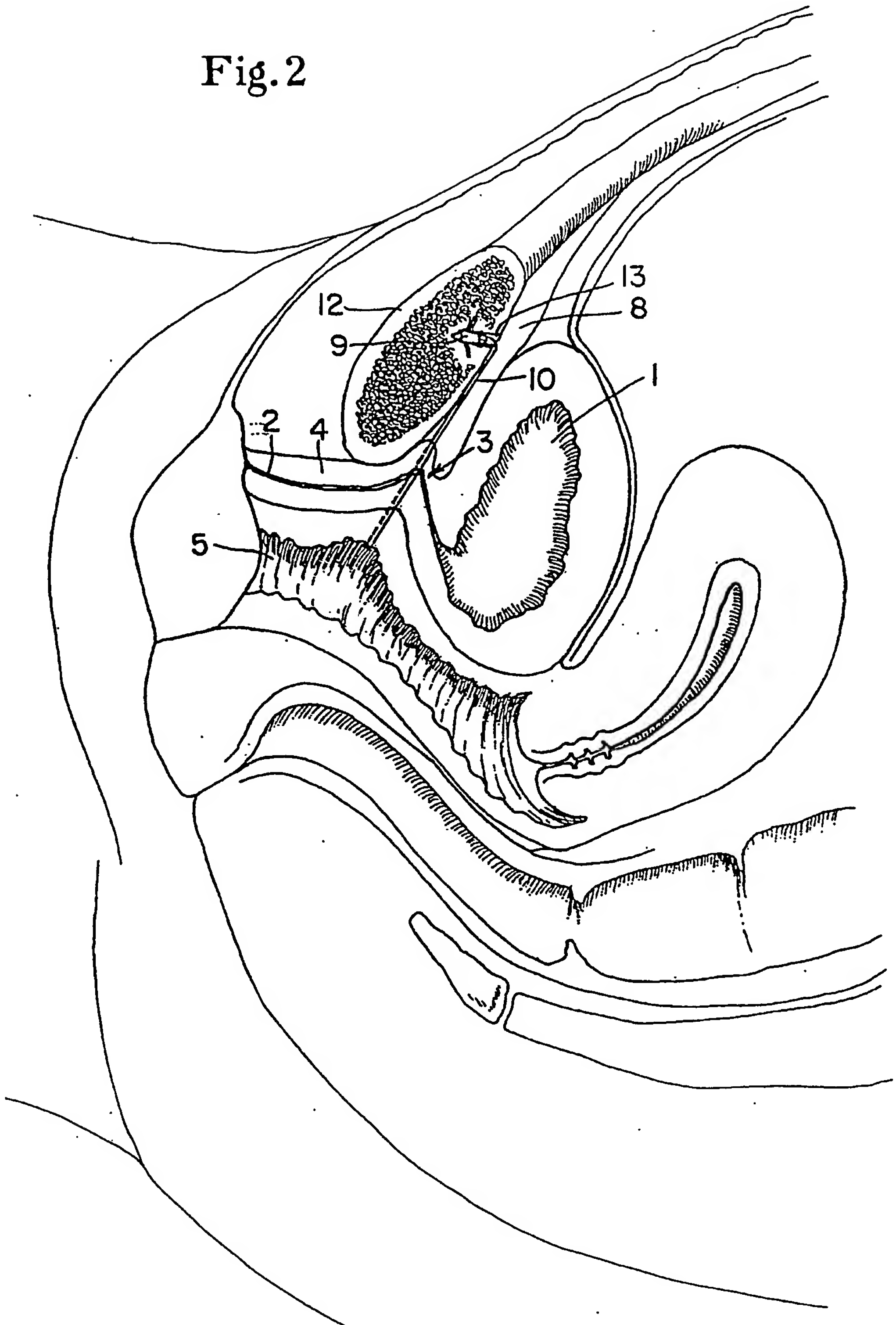


Fig.2



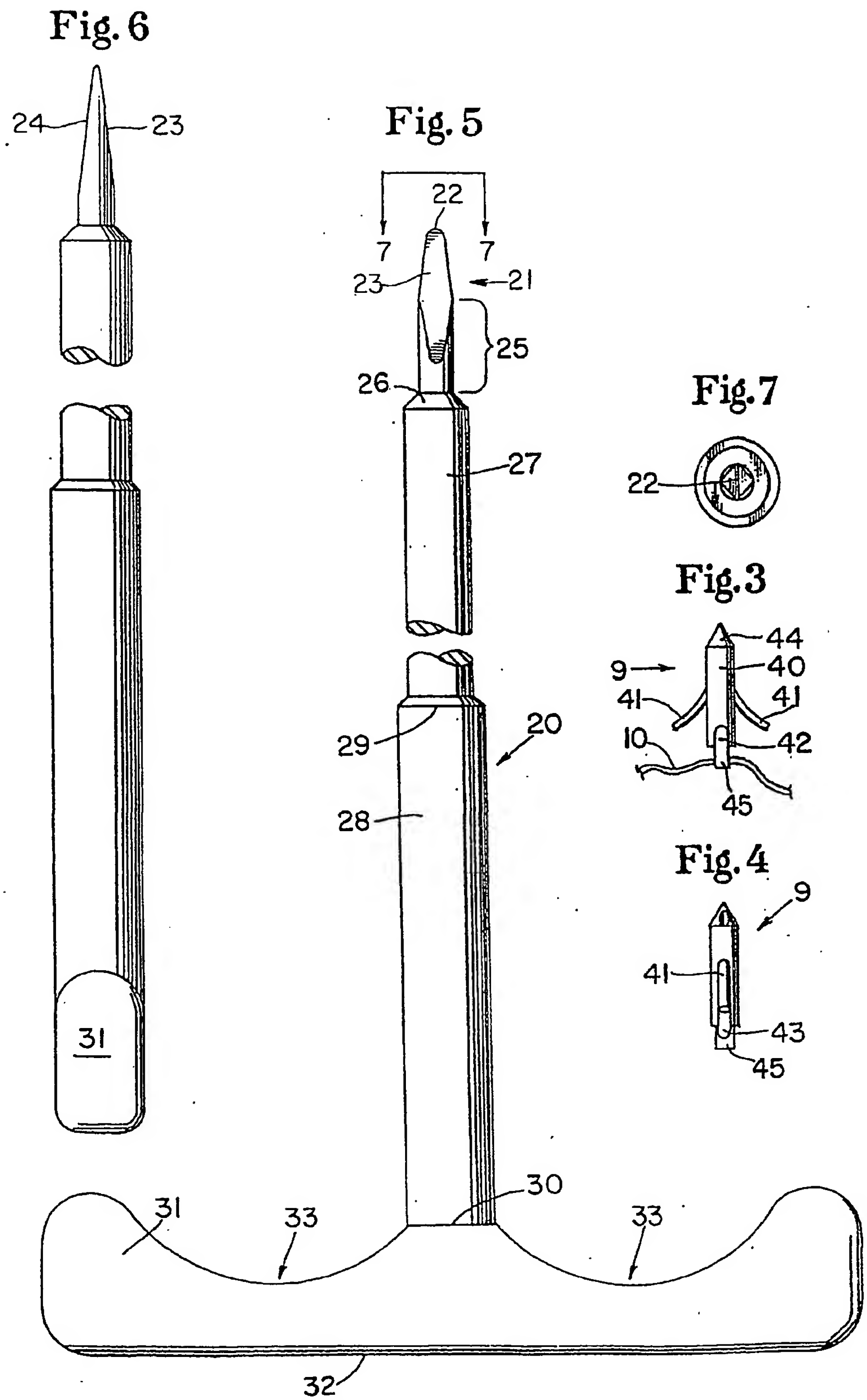


Fig. 6
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Fig. 5
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Fig.7
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Fig. 4
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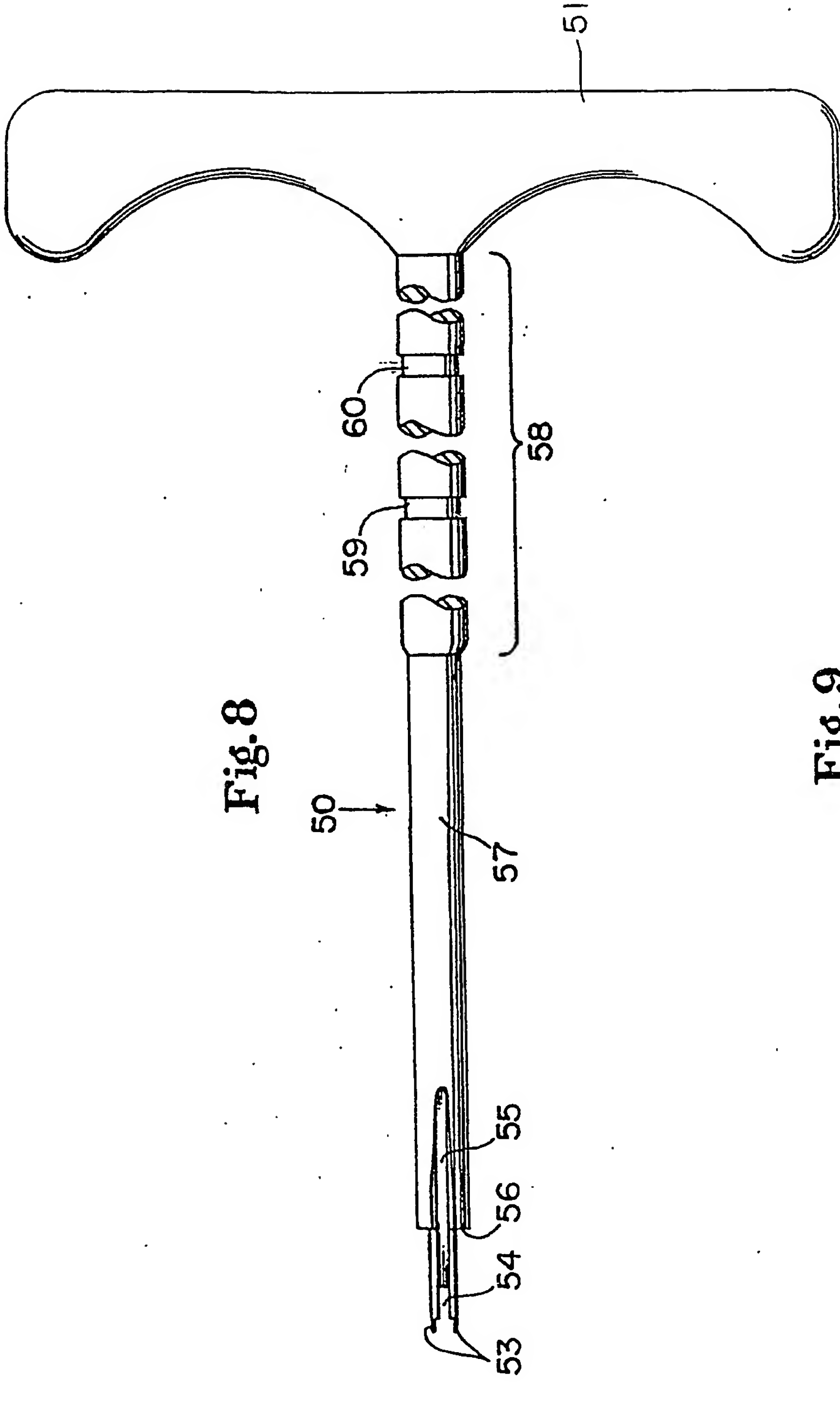

Fig. 8

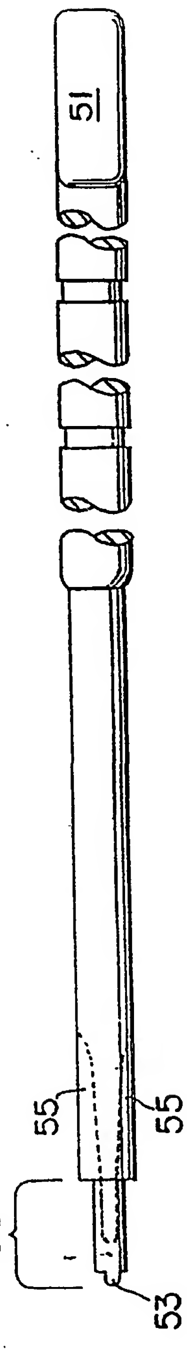

Fig. 9

Fig. 10

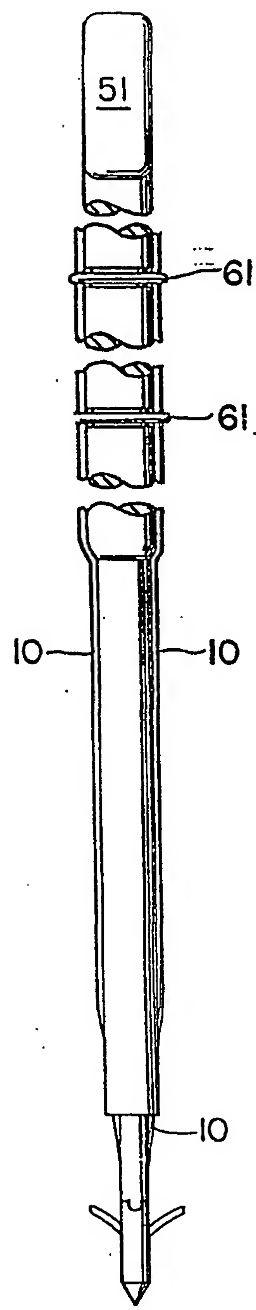

Fig. 12

Fig. 11

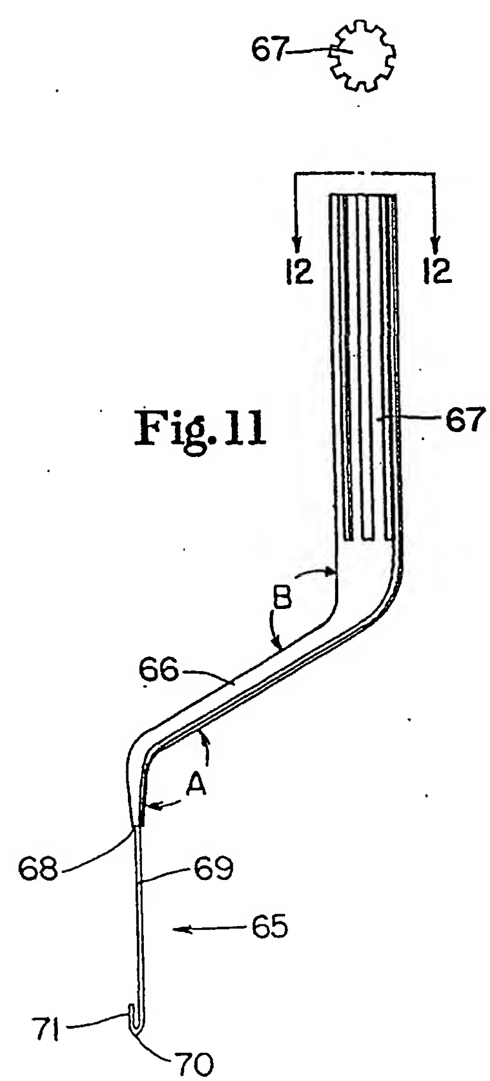

Fig. 13

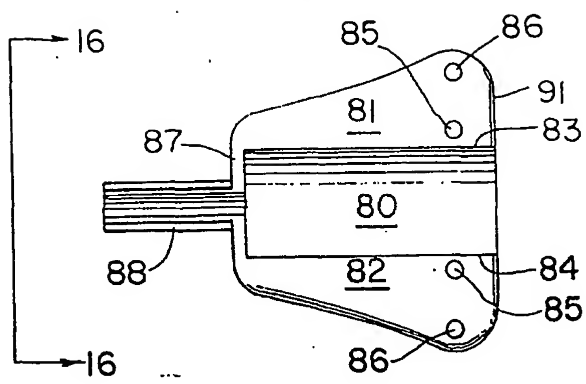

Fig. 14

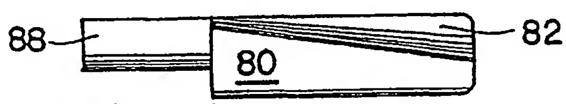

Fig. 15

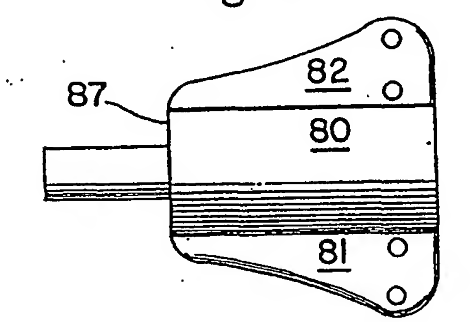

Fig. 16

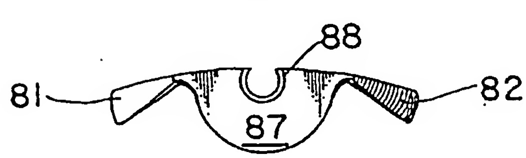

Fig. 17

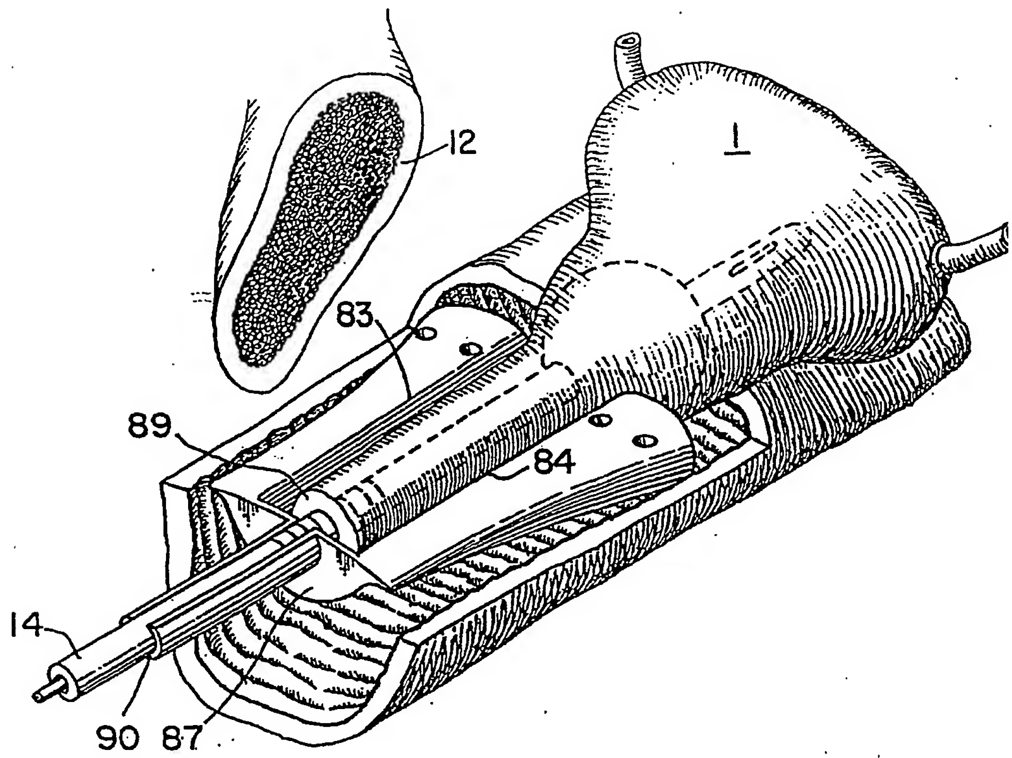

Fig. 18

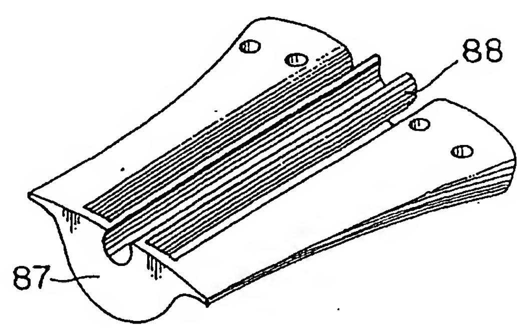

Fig. 19

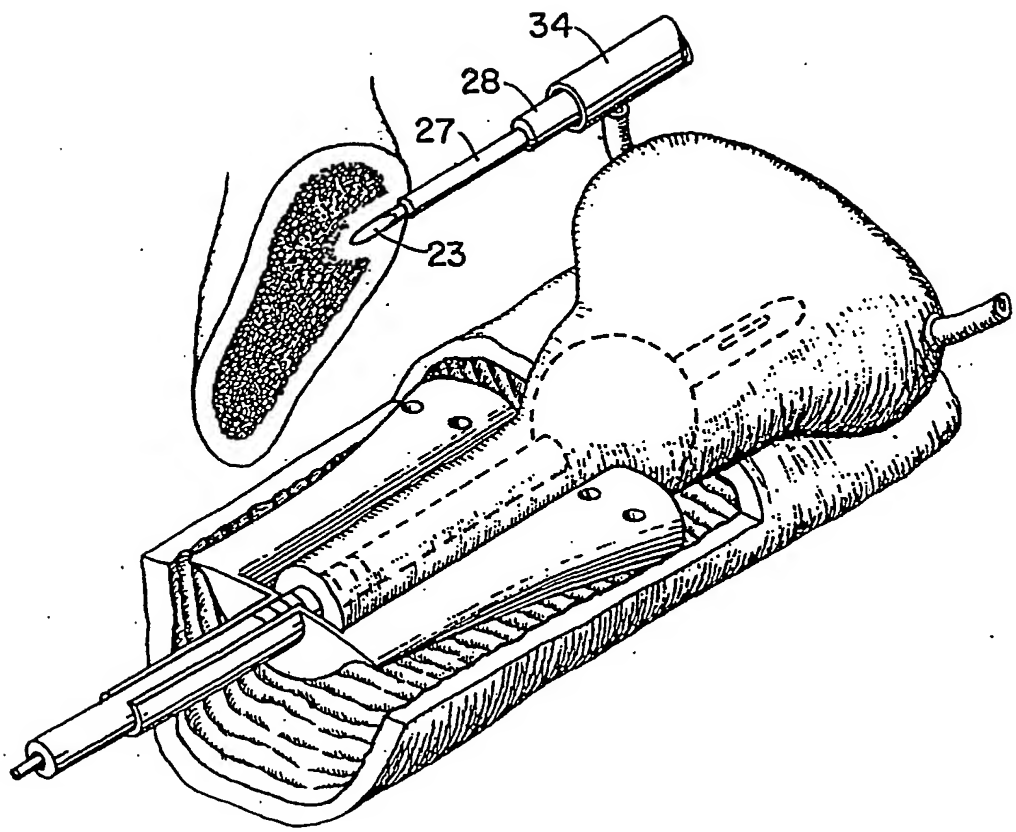

Fig. 20

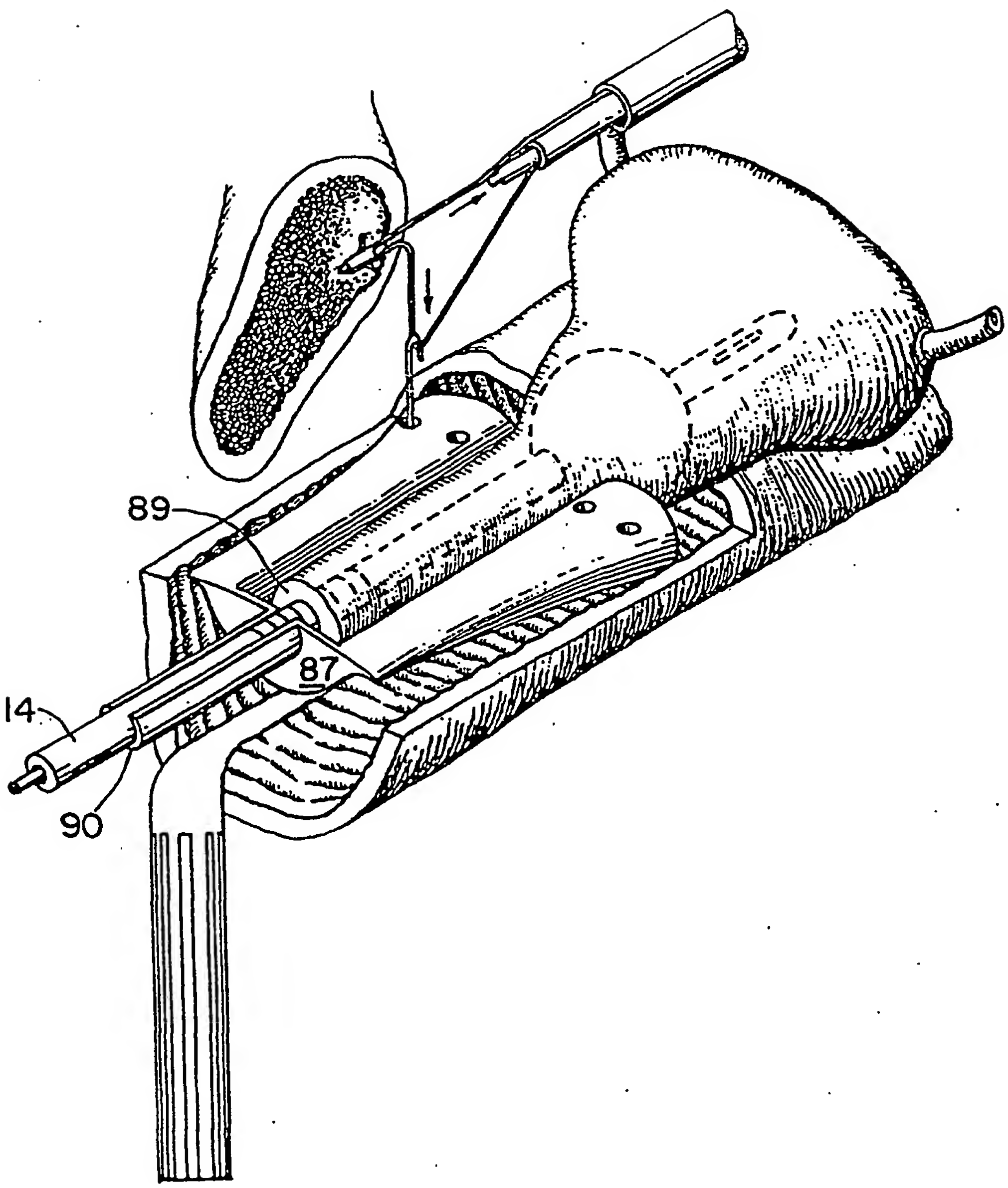

Fig. 21

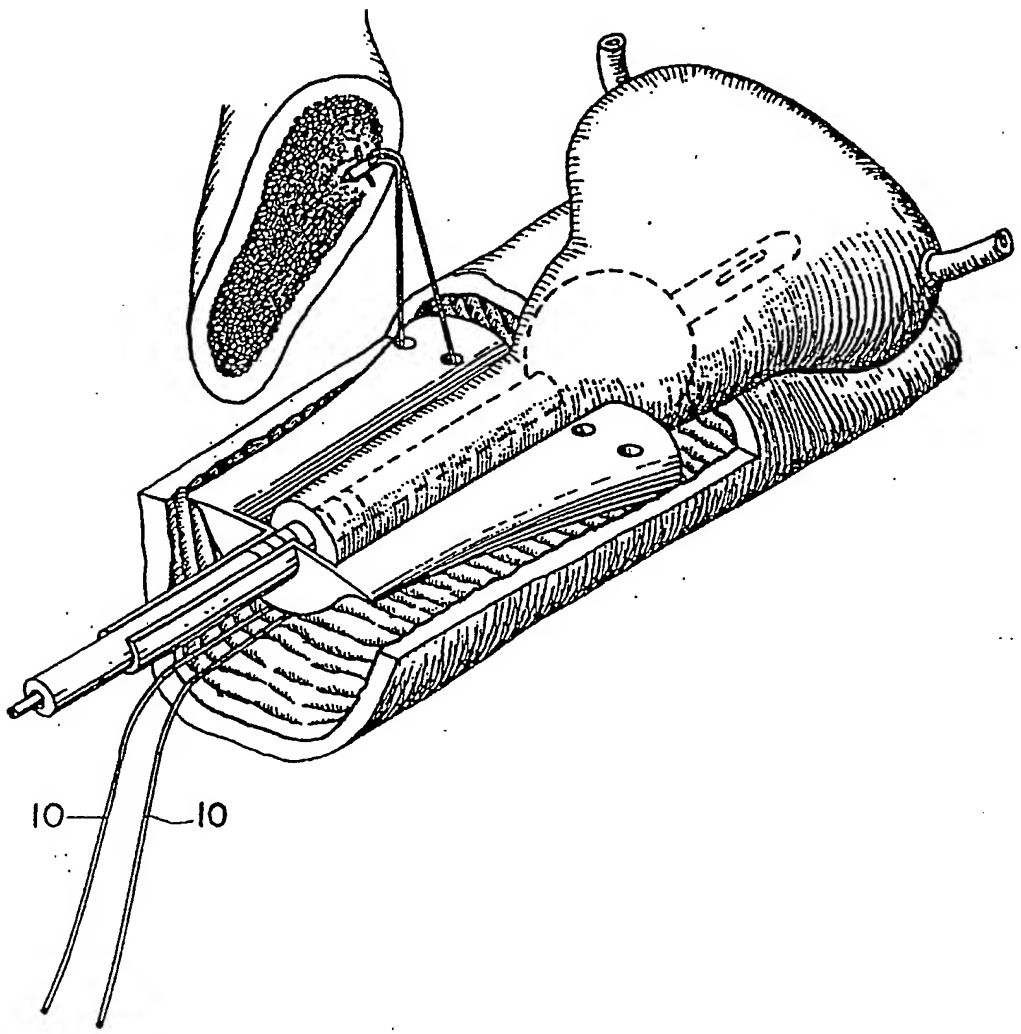

Fig.22

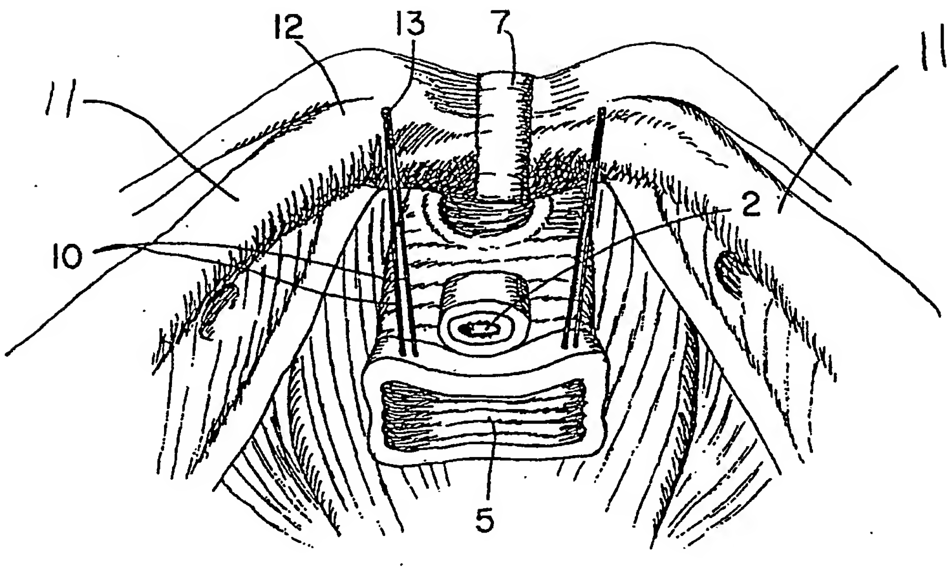

Fig. 23

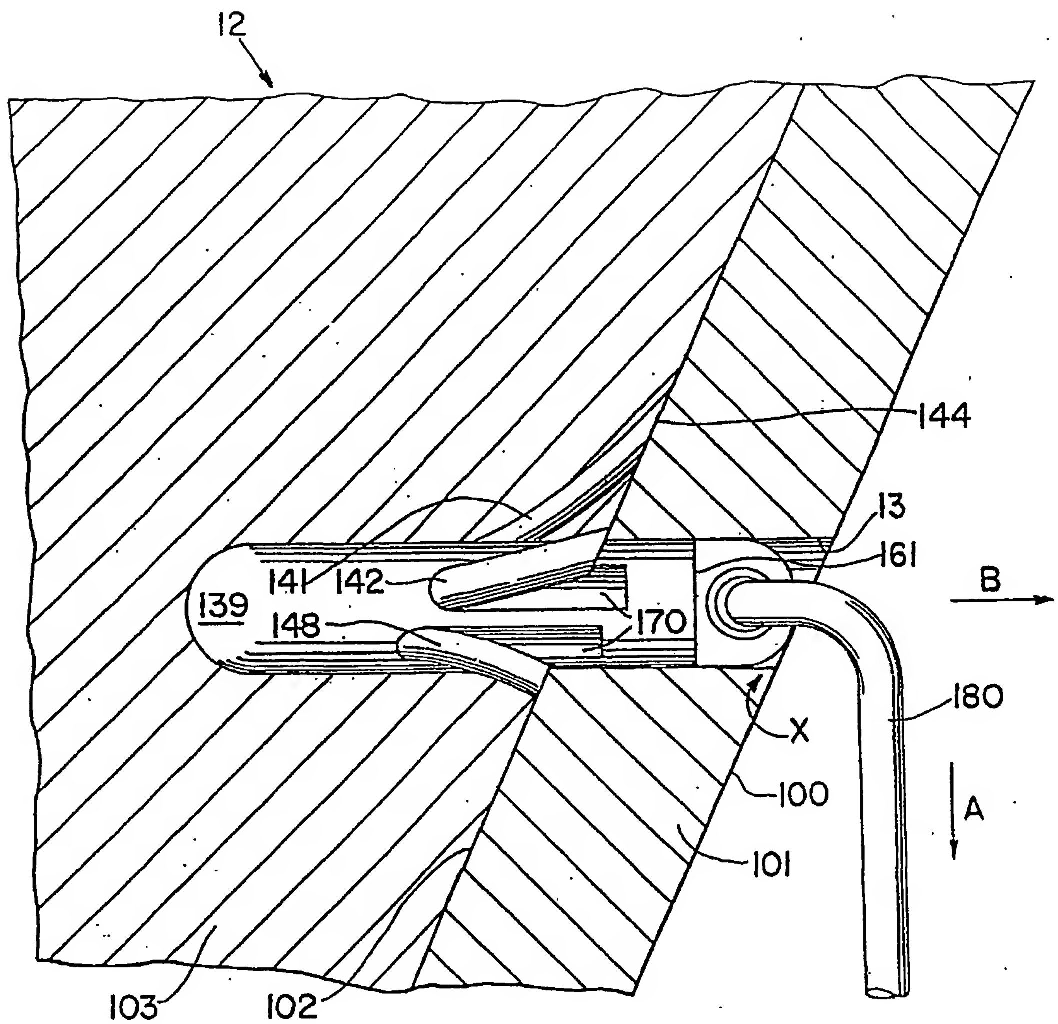

Fig. 24

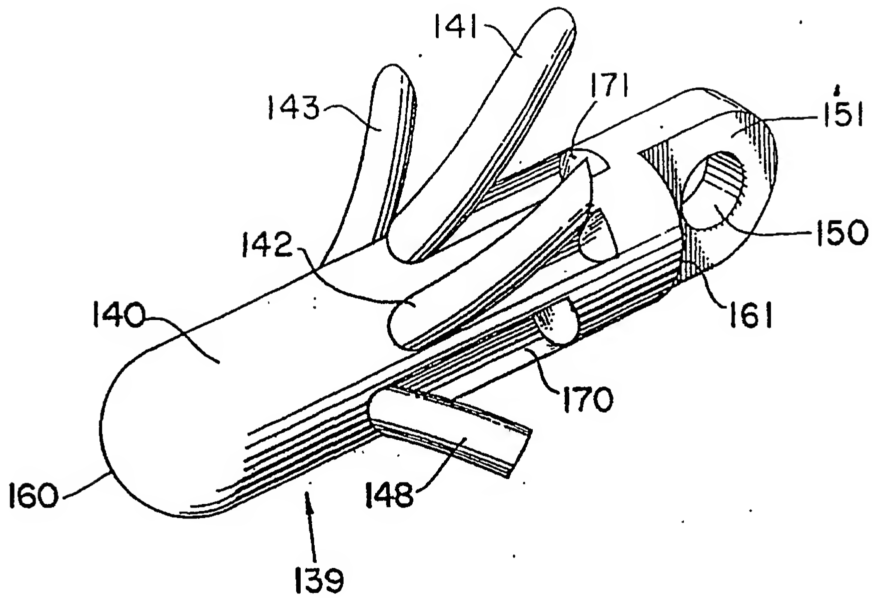
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Fig. 25

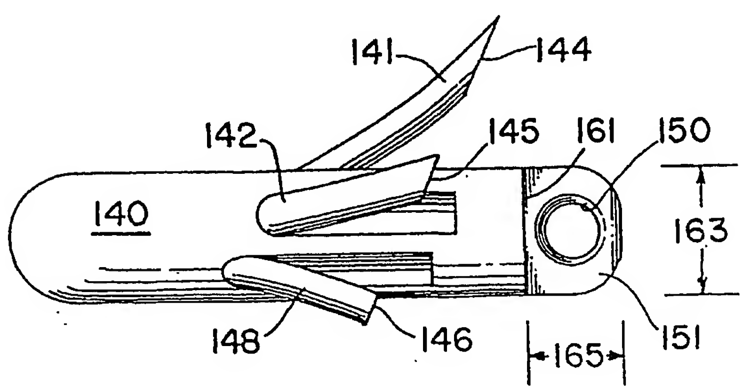
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Fig. 25a

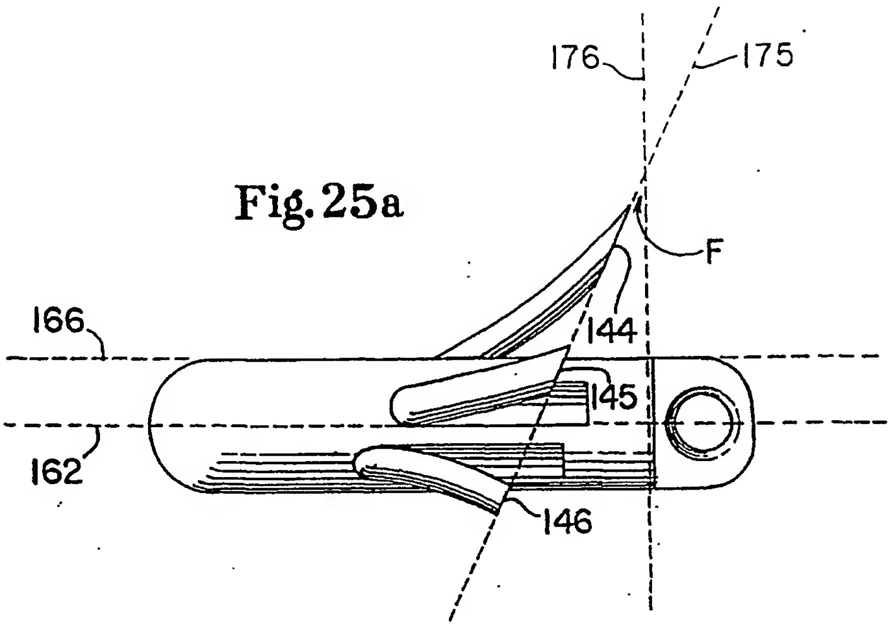


Fig. 26

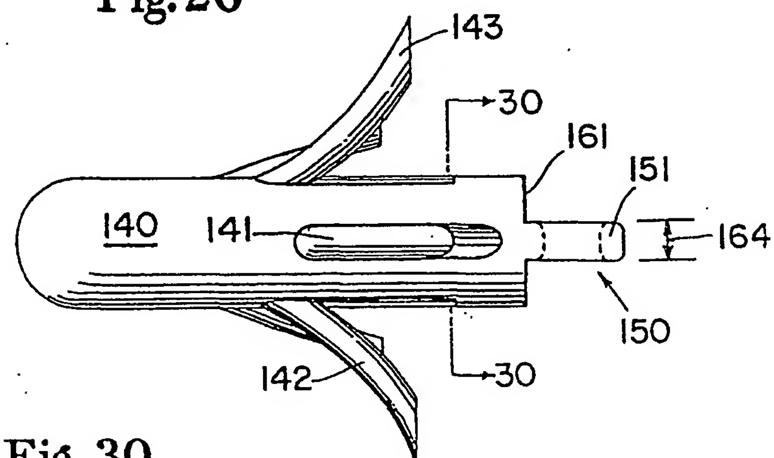


Fig. 30

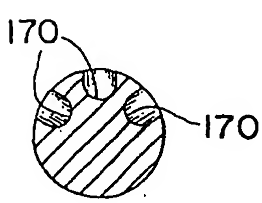


Fig. 27

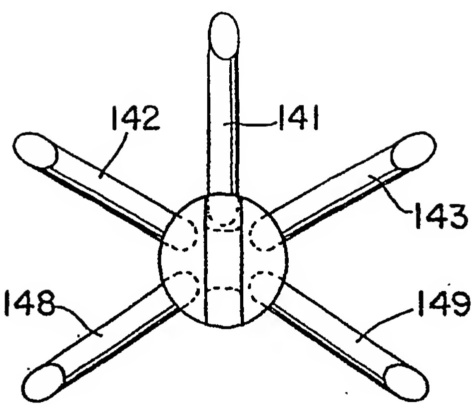


Fig. 28

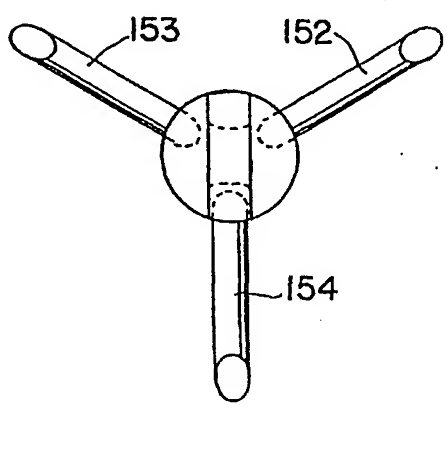
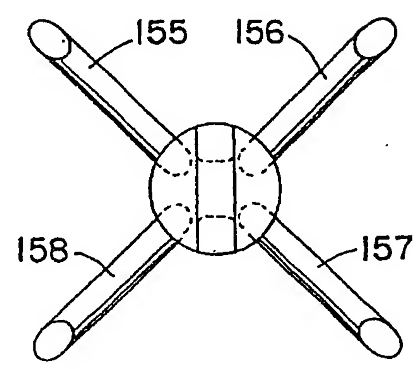


Fig. 29



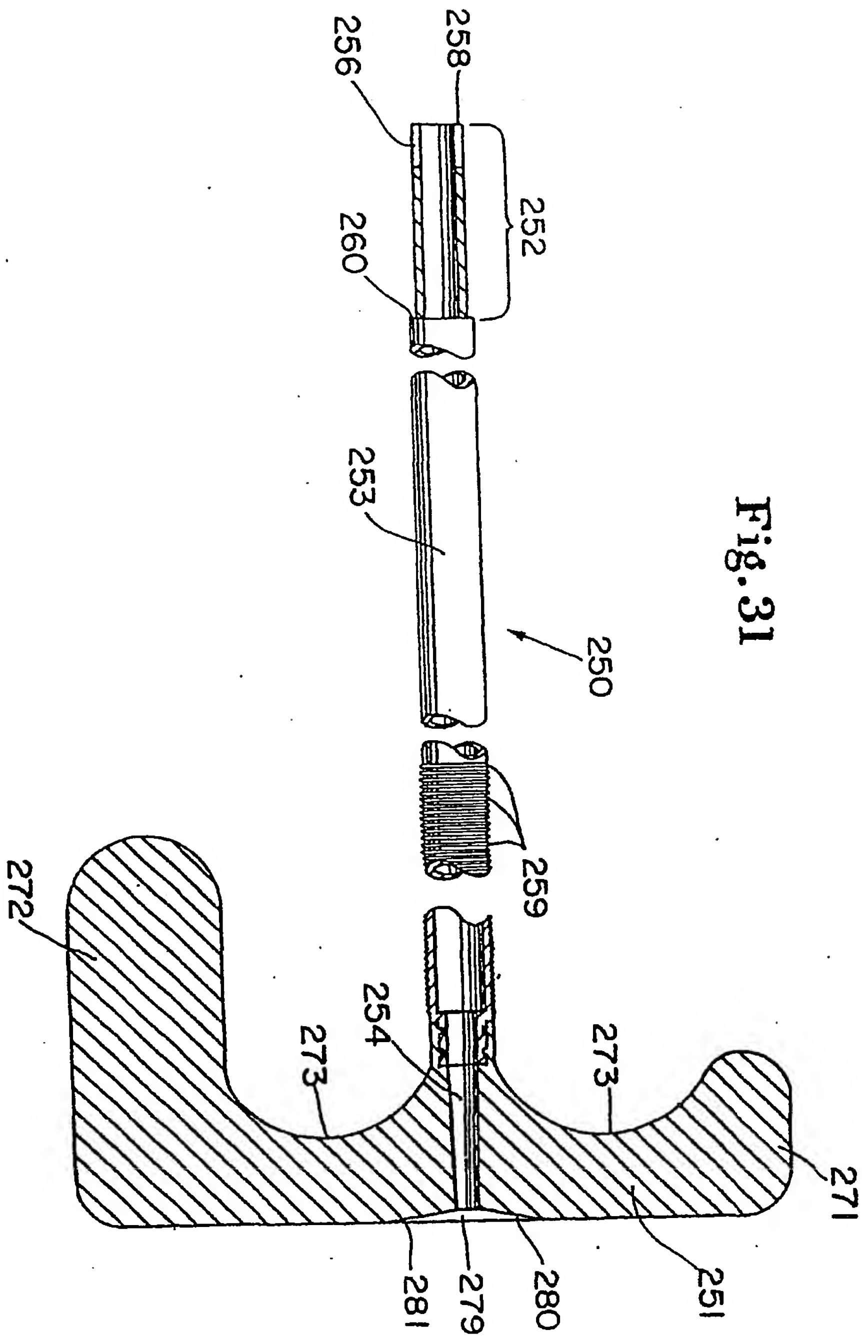

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Fig.31

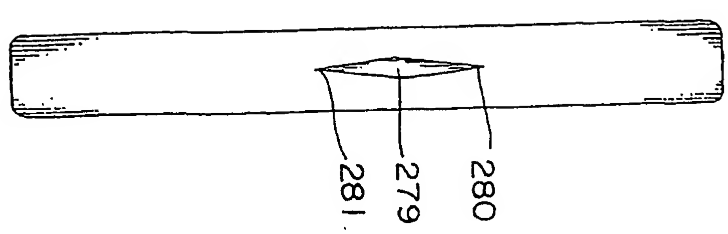
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Fig.36

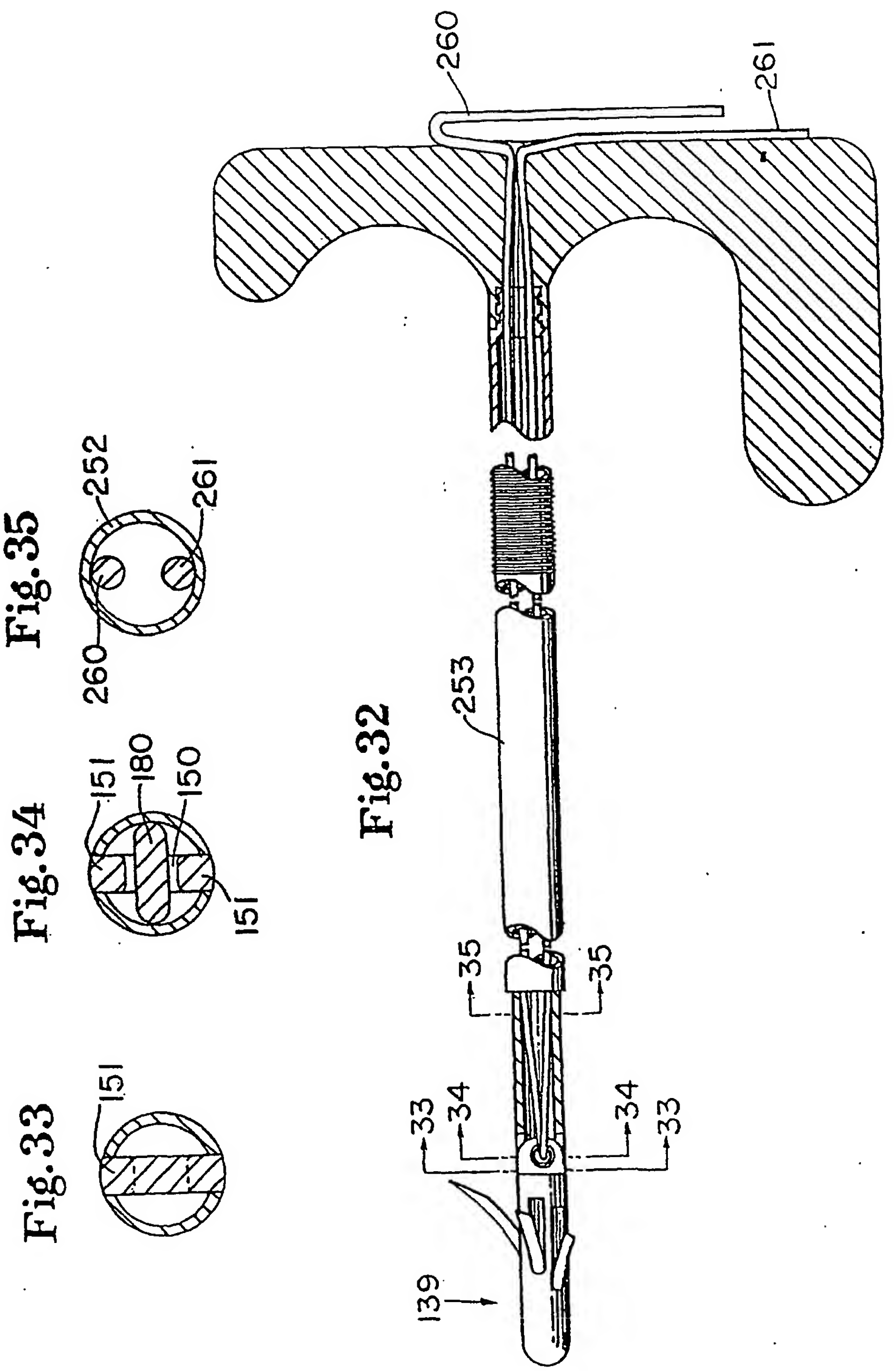


Fig.35

Fig.34

Fig.33

Fig.32

Fig. 38

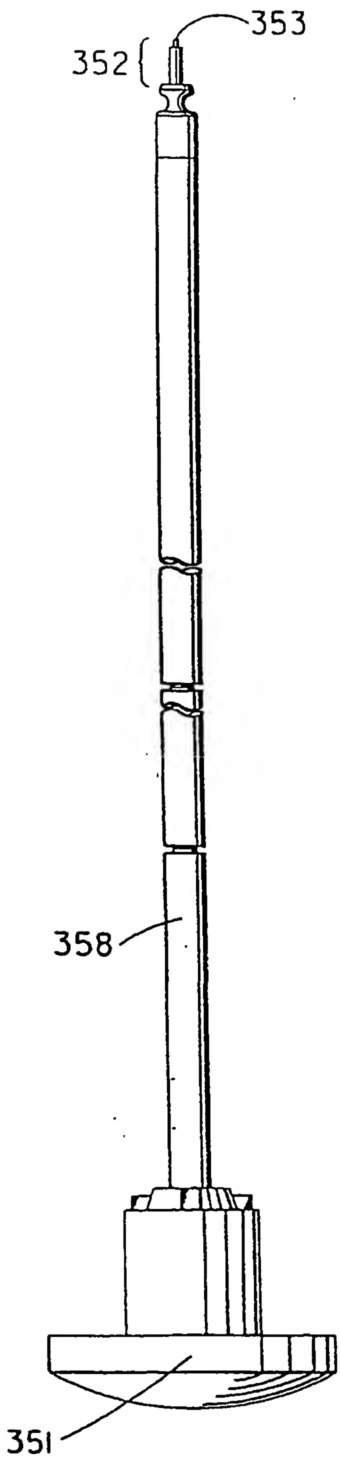
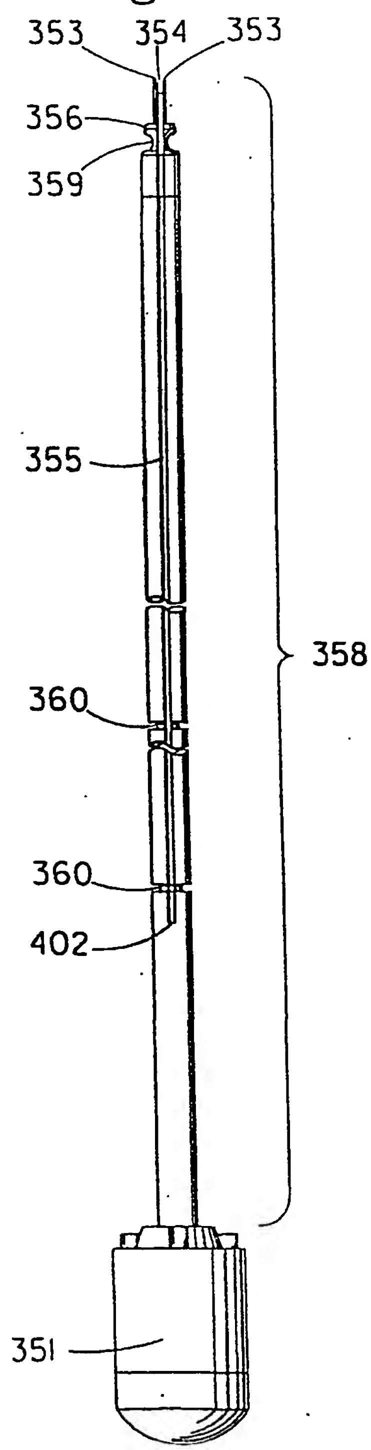


Fig. 37



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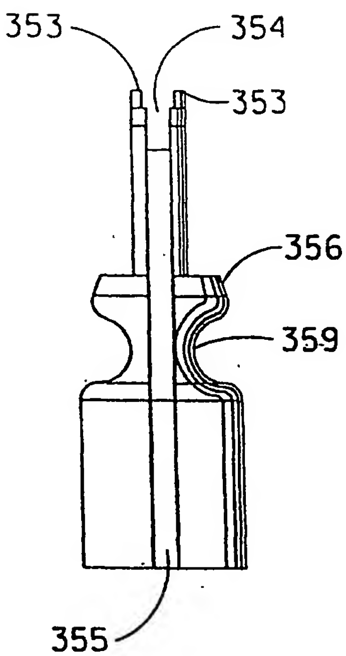

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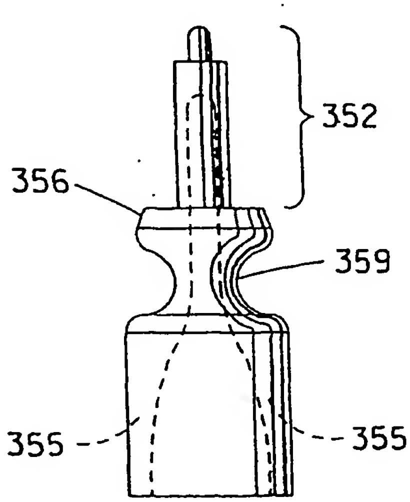
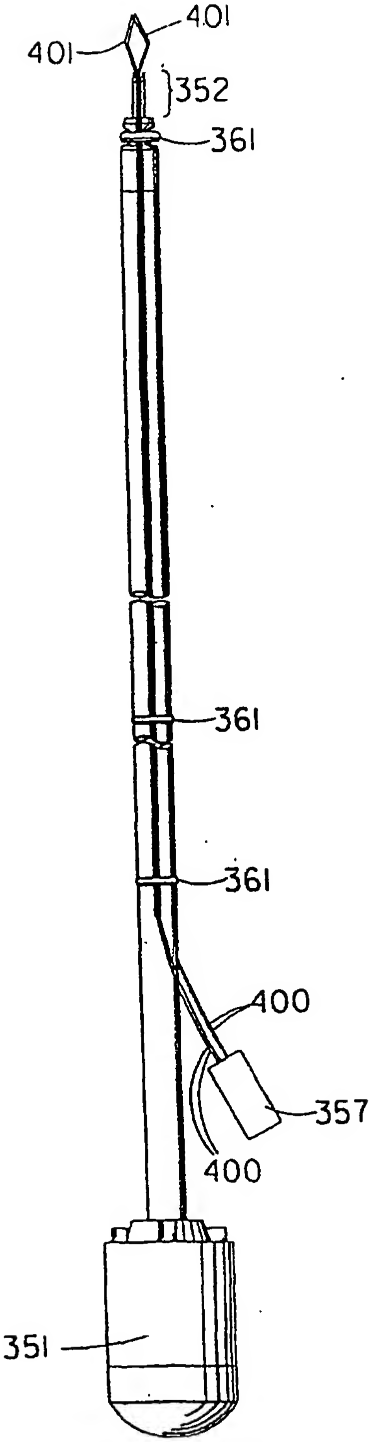
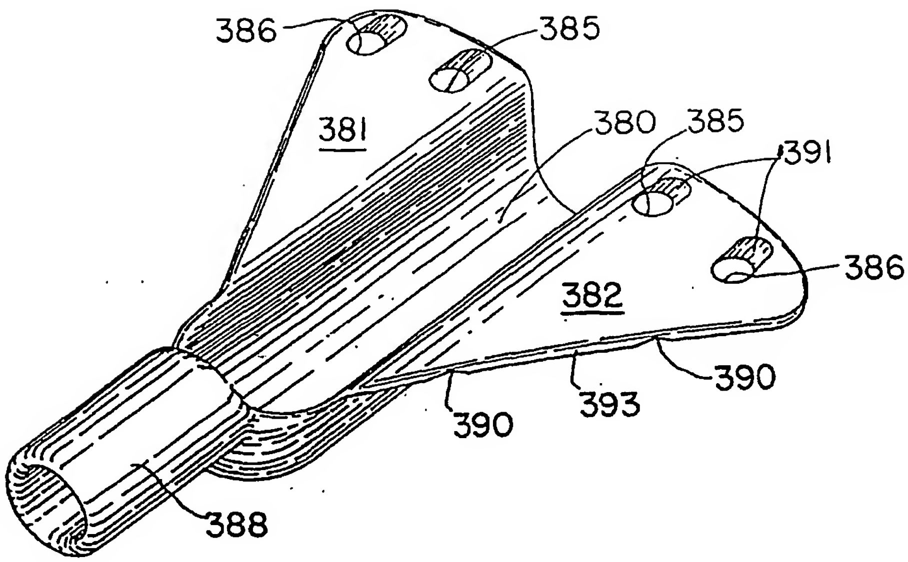


Fig. 41





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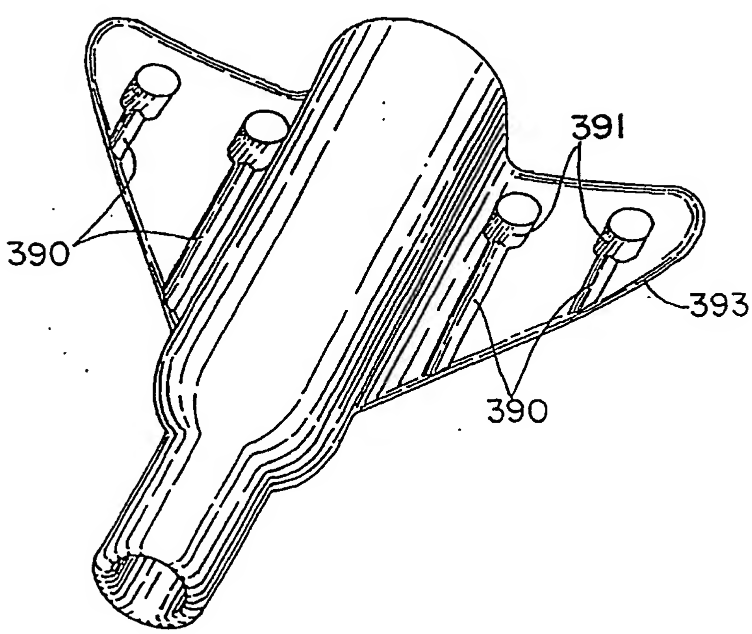


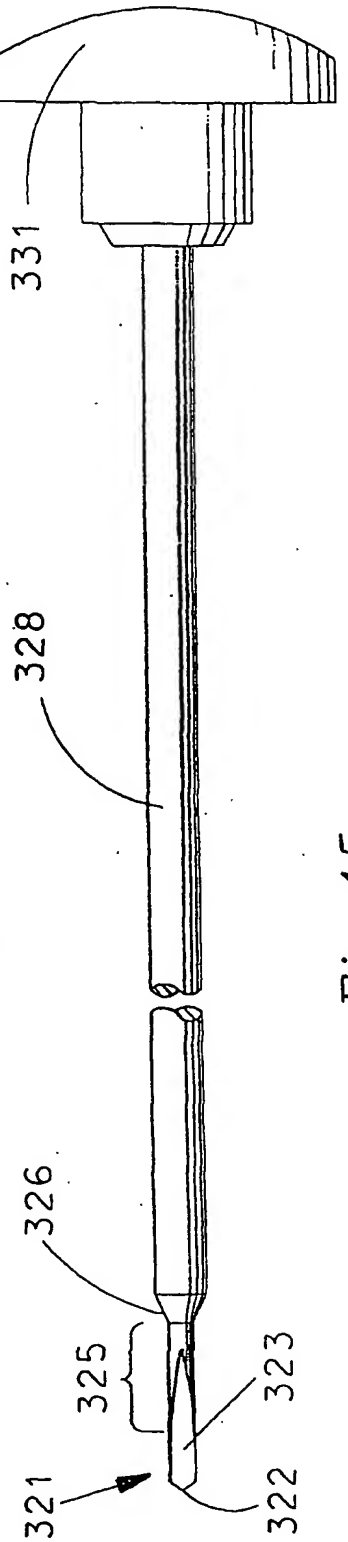


Fig. 44

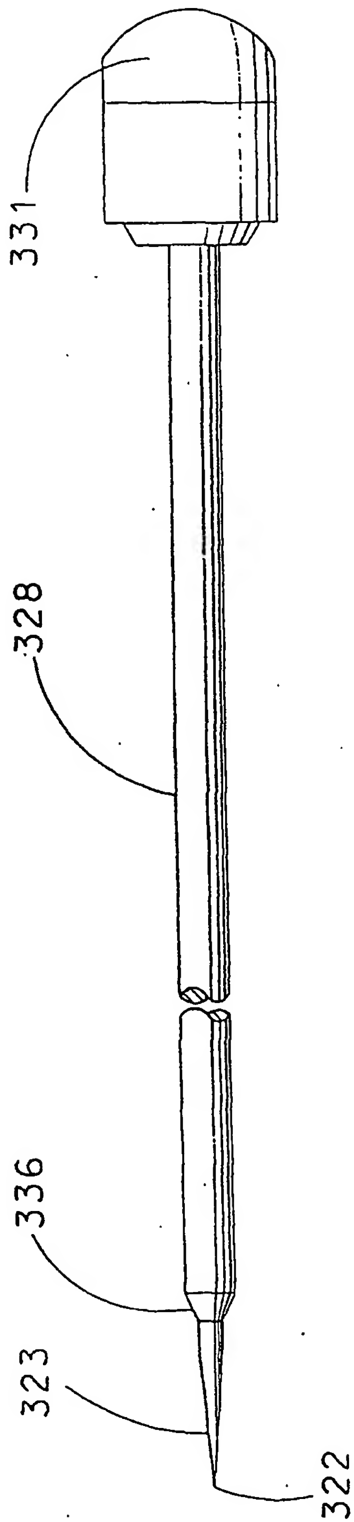


Fig.45

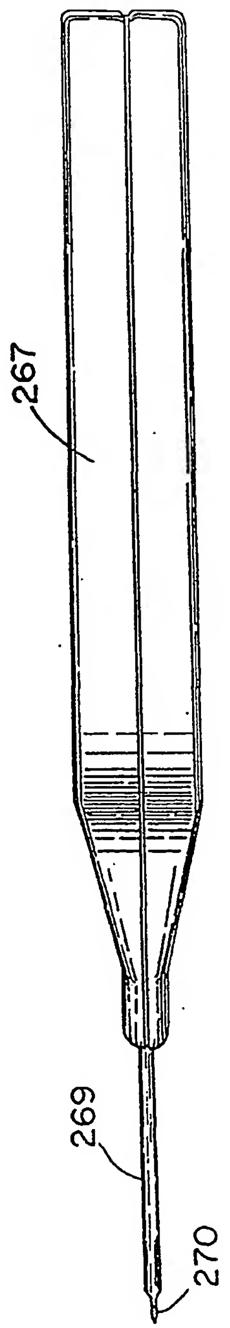


Fig.47

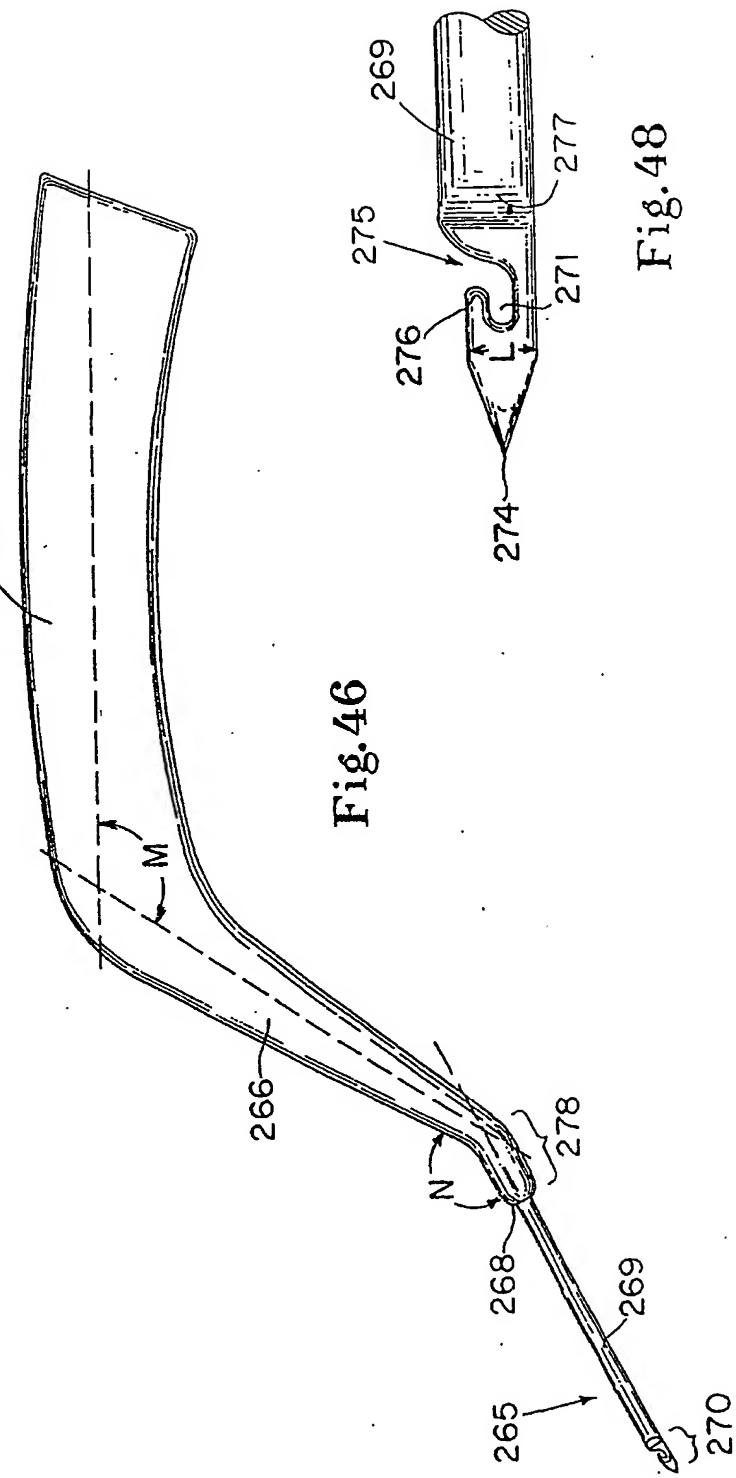
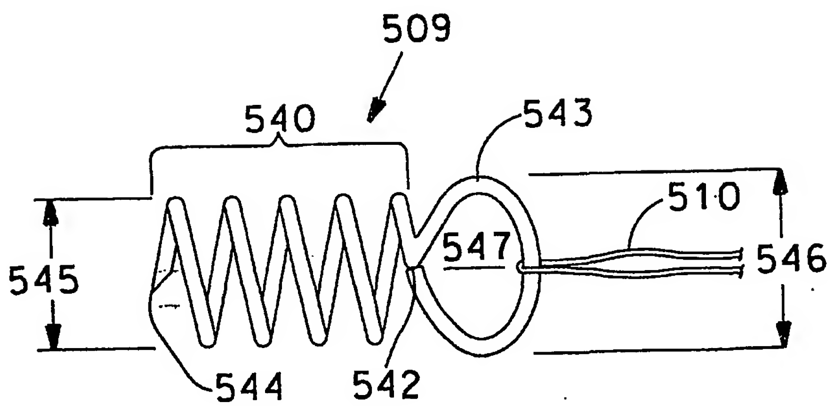


Fig.46

Fig.48

Fig. 49



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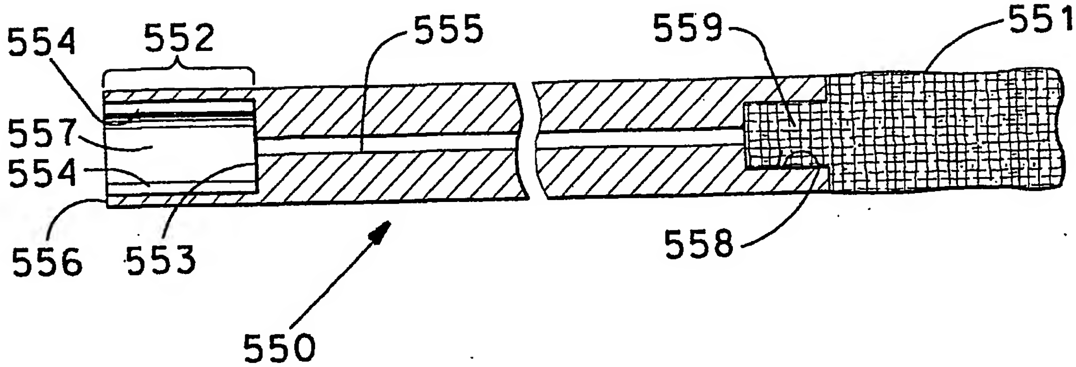

Fig. 51

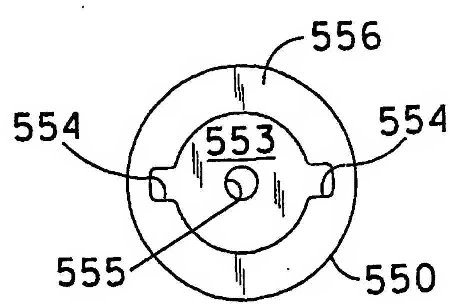

Fig. 52

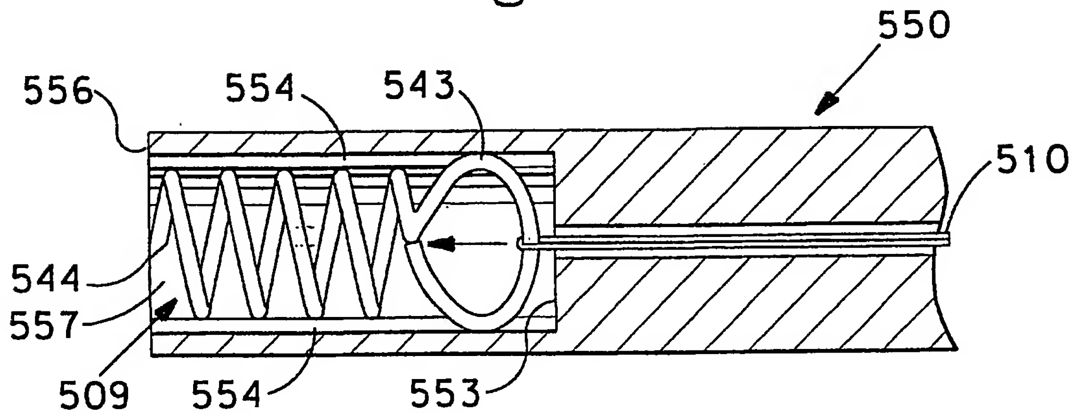
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Fig. 53

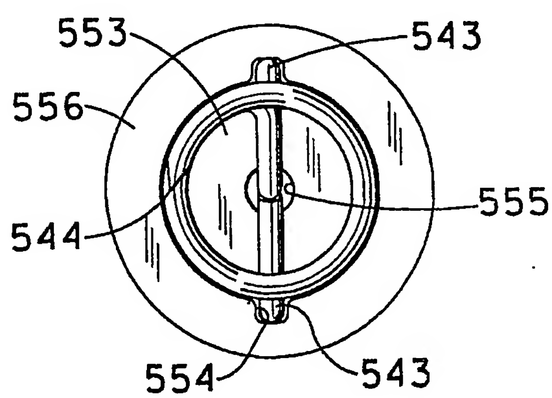
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Fig. 54

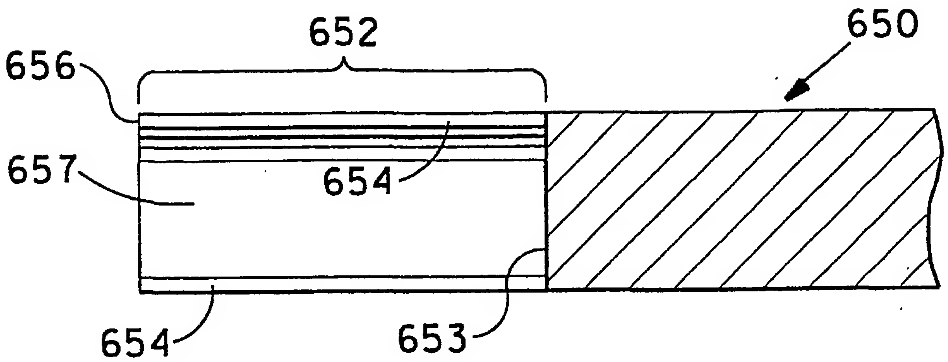


Fig. 55

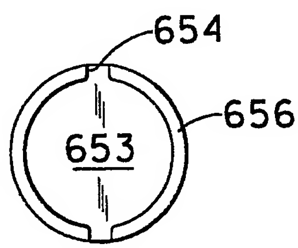
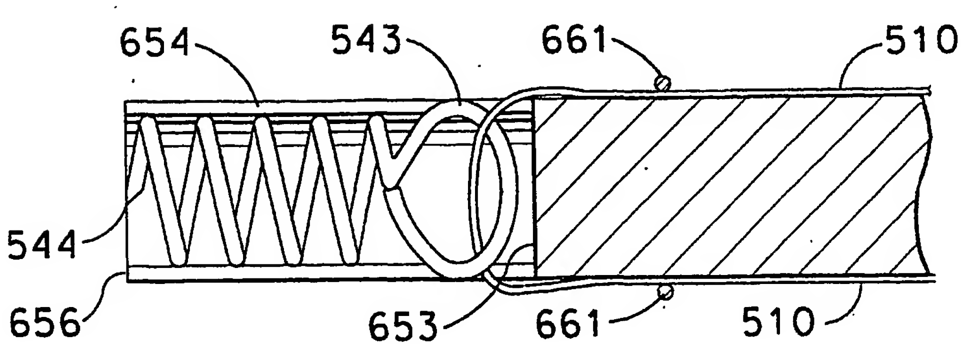


Fig. 56



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/35386

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/04
US CL :606/232
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72, 73, 104, 232; 128/898; 604/1, 11, 18, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS
search terms: incontinence, suture, anchor, helical, Cooper, vagina, dissect, absorbent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,439,457 A (YOON) 08 August 1995, entire document.	9
Y	US 5,591,163 A (THOMPSON) 07 January 1997, entire document.	7,16-23
Y	US 5,626,613 A (SCHMIEDING) 06 May 1997, entire document.	4-23
X	US 5,662,683 A (KAY) 02 September 1997, figures 1-3.	1
X	US 5,728,116 A (ROSENMAN) 17 March 1998, figure 18.	1-3
Y,P	US 6,096,041 A (GELLMAN et al.) 01 August 2000, col. 1, line 52 to col. 2, line 3.	17-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
22 MARCH 2001	20 APR 2001

Name and mailing address of the ISA/US	Authorized officer
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